

European Standardization Organizations

Welcome to this webinar

Harmonized European standards: Drafting standards compliant with EU legislation

*We start at
14:00 CEST*

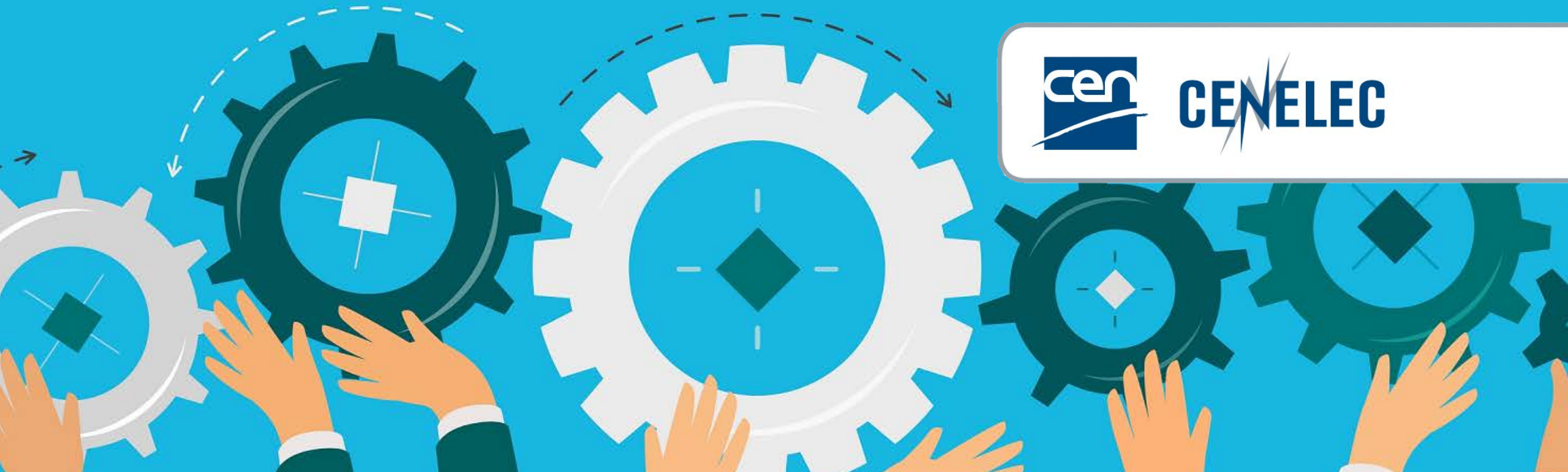
Your webinar moderator



Els SOMERS

Project Manager Engagement
Governance & Partnerships

esomers@cencenelec.eu



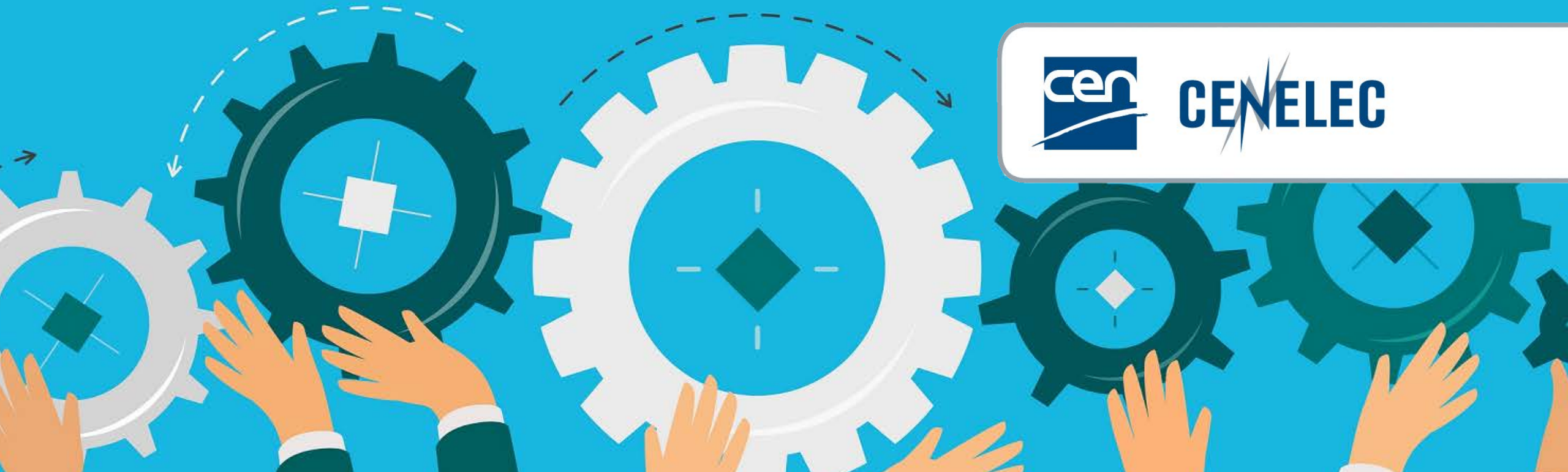
European Standardization Organizations

Introduction

Cinzia Missiroli, Director Standardization & Digital Solutions



- 1) New Approach, New Legislative Framework & Standardization requests
- 2) HAS assessment system update
- 3) Coffee break
- 4) Elaboration of harmonized standards
- 5) Drafting hENs in the international context: VA and FA
- 6) Citation of hENs in OJEU
- 7) Q&A



European Standardization Organizations

New Approach, New Legislative Framework & Standardization Requests

Catherine Vigneron, Account Manager Energy & Living



EU product harmonization legislation

- ▶ New Approach
- ▶ New Legislative Framework

Standardization Requests

- ▶ Initiation
- ▶ Process
- ▶ Specificities
- ▶ Look and feel

EU product harmonization legislation

Old Approach

- ▶ National legislation
- ▶ Product technical requirements in legislation

New Approach (NA)

- ▶ Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards
- ▶ Large family of products



New Approach directives/regulations

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

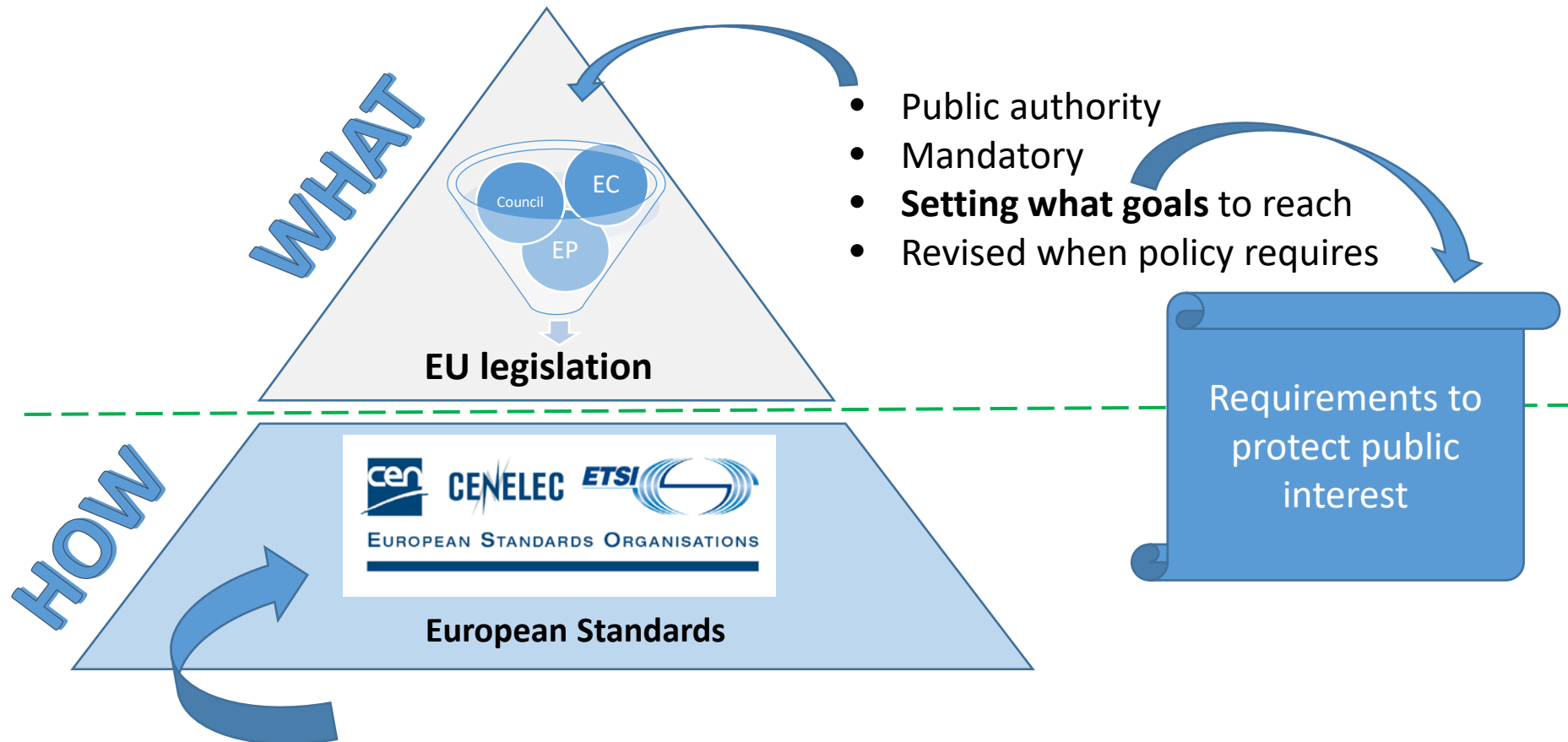
Reference to standards

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

New Legal Framework (NLF)

- ▶ Entered into force 1 January 2010
 - ▶ Increase consistency (harmonization) across all NA Directives
 - ▶ Complements New Approach
- Decision N° 768/2008/EC on establishing a common framework for the marketing of products

New Approach/NLF principle



European law regulates important industrial sectors:

- ▶ Machinery, Lifts
- ▶ Construction
- ▶ Low voltage equipment
- ▶ Pressure equipment
- ▶ Packaging and packaging waste
- ▶ Medical devices
- ▶ Railways

Specificities

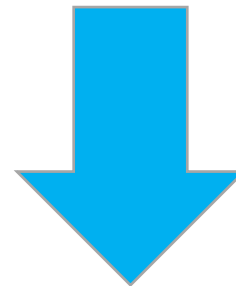
- ▶ Assessment of compliance with legal requirements – *details later*
- ▶ Annex ZA/ZZ obligatory for candidate harmonized standards (hENs) – *details later*
- ▶ Only when cited in the Official Journal of the European Union → European Standards give presumption of conformity to the Essential Requirements covered by the hENs
- ▶ Application of hEN remains voluntary → other means to show conformity are allowed



Standardization Requests

At European Commission request

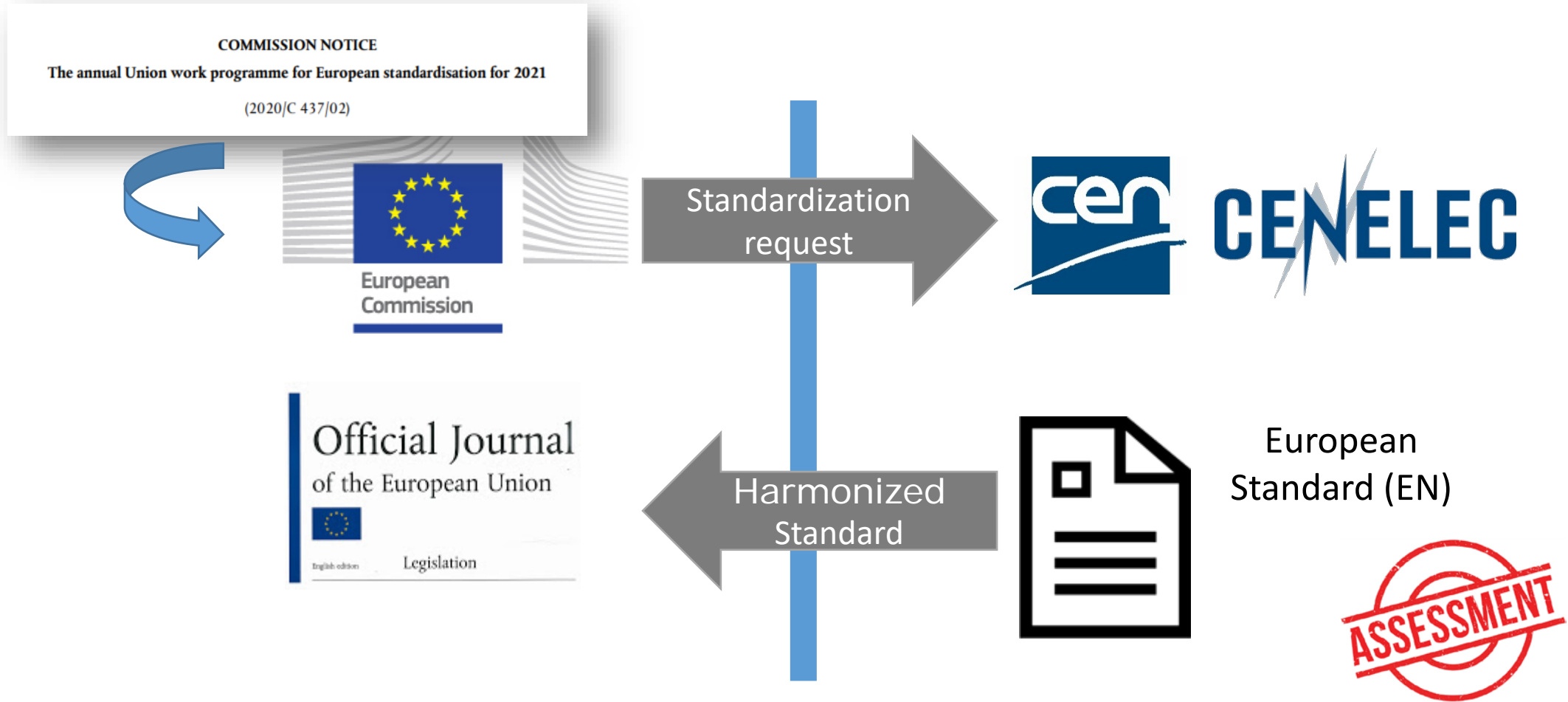
Standardization Request = Commission Implementing Decision



Regulation 1025/2012

CEN and CENELEC develop Harmonized Standards in support of EU legislation and/or policies

Standardization Requests - Process



Standardization Request a **precondition** for citation of harmonized standards in OJEU

Regulation 1025/2012 (art 8) - Annual Union Work Programme

- ▶ Identify strategic priorities for European standardisation
- ▶ **First** reference to upcoming standardization requests

EUROPEAN COMMISSION

COMMISSION NOTICE

The annual Union work programme for European standardisation for 2021

(2020/C 437/02)

Development process described in EC Vademecum on European standardization (Part II)

- ▶ **Consultation stakeholders** (e.g. CEN and CENELEC) and Members States
- ▶ CEN and CENELEC establish **Standardization Request Ad Hoc Groups**
 - Group established for any new draft SReq that **ensures coordination** and input from all relevant stakeholders (incl. TCs) during the drafting and approval of Standardization Requests → group advises the Technical Boards
 - **This consultation is a key step**



- ▶ Voted by Members States (Committee on Standards)
- ▶ Submitted to CEN and/or CENELEC for **acceptance/rejection** (1 month art. 10)
- ▶ Have an **expiry** date
- ▶ If work item is not in the Standardization Request (Annex) → **no OJEU citation**
- ▶ Standardization Request can be revised → **full approval process**
- ▶ All Standardization Requests are **available** → [database](#)

Standardization Requests – Look & feel



Article 1

Requested standardisation activities

1. The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are requested to revise the existing harmonised standards listed in Table 1 of Annex I to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745 for medical devices by the deadlines set in that Annex.
2. CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices by the deadlines set in that Annex.

ANNEX I

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(1)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 285:2015 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2.	EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2024



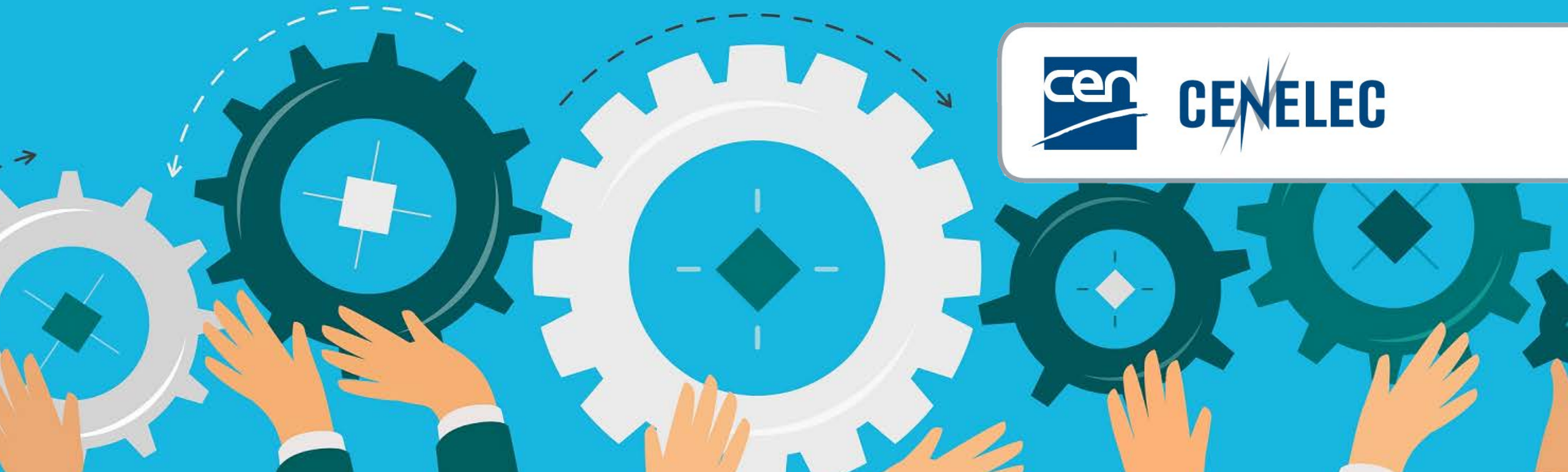
European Standardization Organizations

Thank you!

Catherine Vigneron, Account Manager Energy & Living

cvigneron@cencenelec.eu





European Standardization Organizations

Update on HAS assessment system

Nuno Pargana, Account Manager Manufacturing



HAS CONTRACTOR = Ernst & Young (EY)

- ▶ 1 April 2018 until 31 March 2022

Formal contact point towards EC and European Standardization Organizations (ESO's):

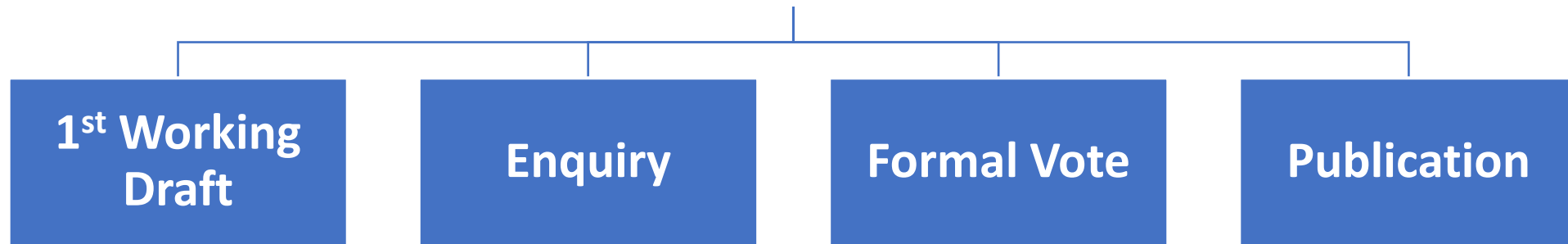
- ▶ Administrative & logistical tasks
- ▶ Horizontal verifications and checks of non-technical nature
- ▶ Evaluation of the assessment results and the effectiveness of the assessment concept

HAS contractor manages the pool of harmonized standards consultants 'HAS Consultants'

Independent expert hired by EY to perform:

- ▶ 'Compliance assessment' of the documents drafted by the ESO's
- ▶ 'Communication' to the technical bodies of the ESO's to give advice **to contribute to compliance of the drafted documents** with the EC's standardization requests →
MEETINGS

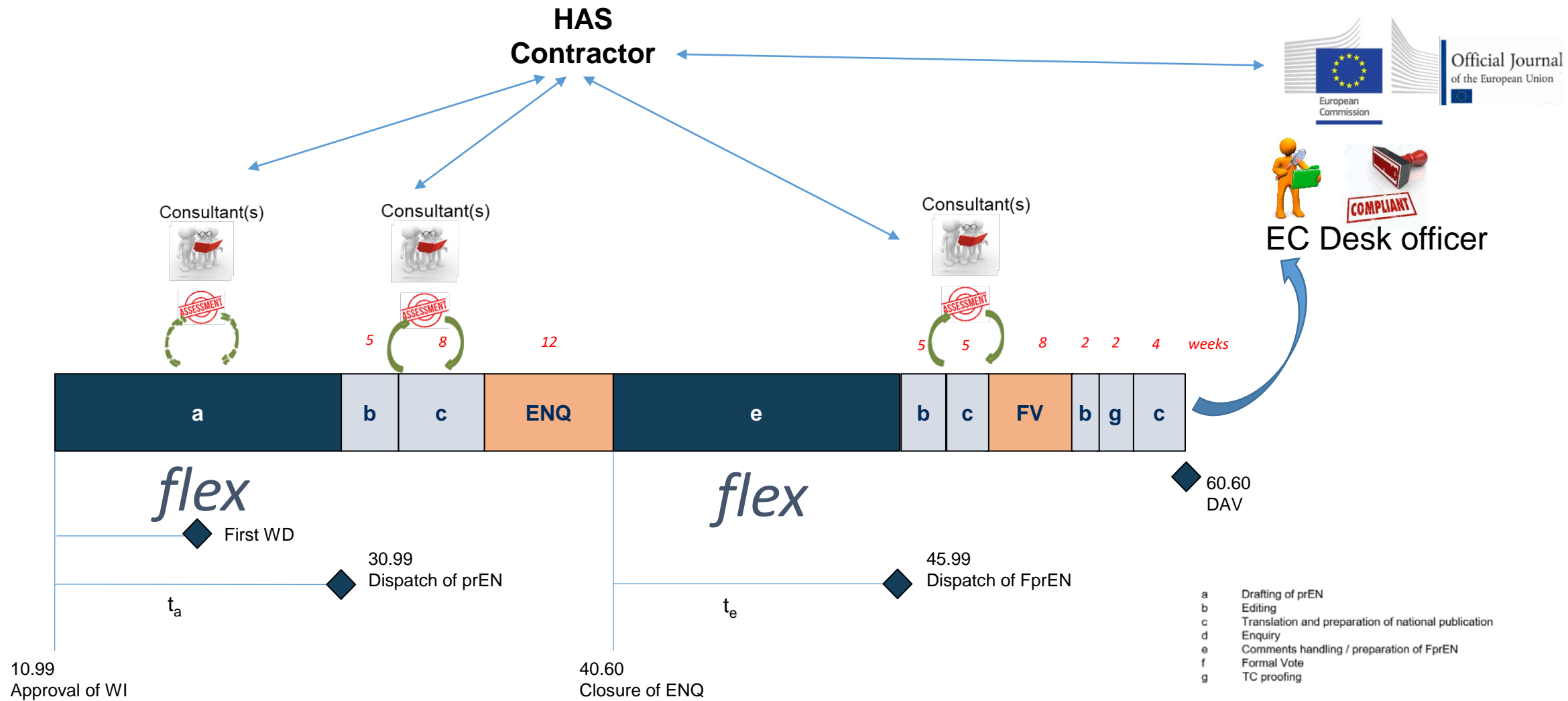
When can assessments be requested?



► Duration:

- normally 5 weeks after notification to HAS CONTRACTOR (EY)

Interaction with standards development



► Outcome

'Compliant'	The publication of the references in the OJ is normally possible without any specific notice
'Partial compliance'	The publication of the references in the OJ could be possible with a notice; such a notice shall be outlined in the report for already adopted standards and for documents assessed before formal vote
'Lack of compliance'	The publication in the OJ is likely not possible before the document is revised

► HAS assessment reports: [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

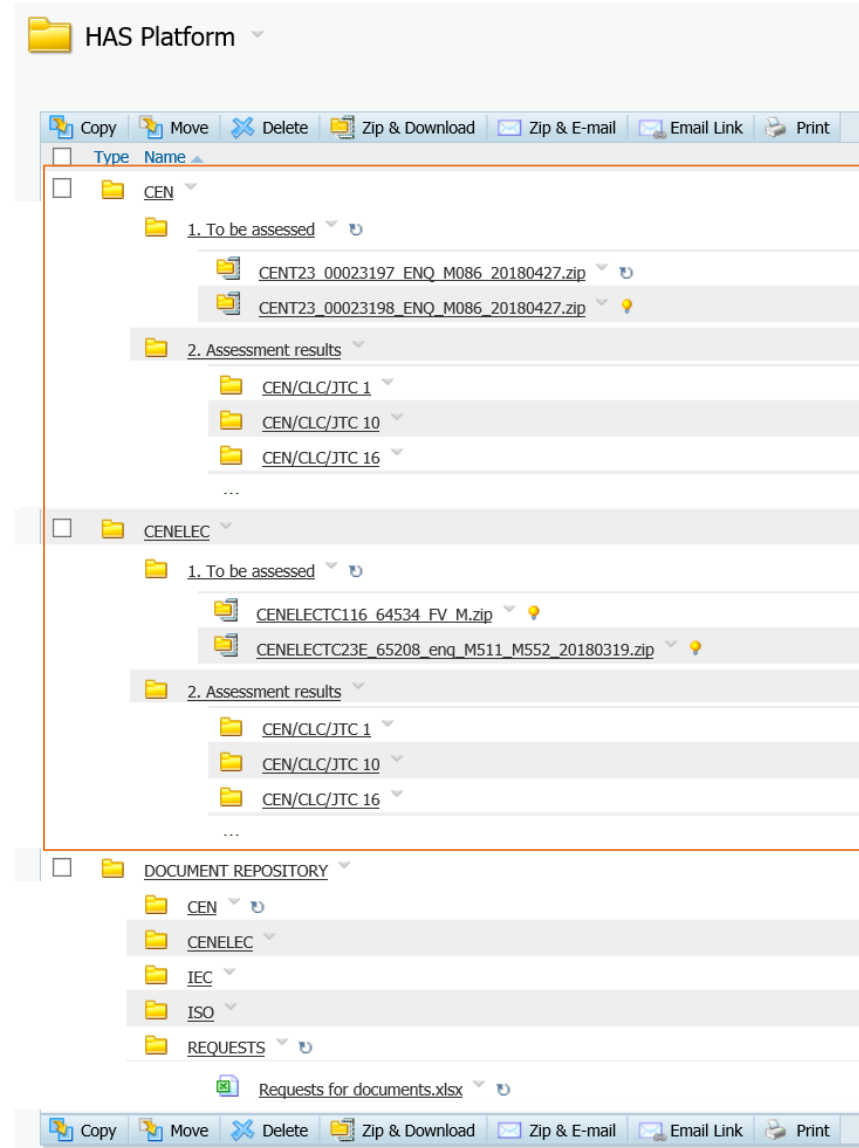
- Compliance** - no 'critical findings' are reported
 - Good or sufficient quality for a compliant document** - no changes required and no critical findings
 - Minor or limited number of changes not affecting compliance** – please indicate those changes in section 2 (other findings)
- Lack of compliance** - 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

1.2 Critical findings leading to a Lack of compliance - Tick relevant boxes for the Critical findings that have been found in the document (and provide details in 1.3 'Additional information on the critical findings', Part B and template of comments)

- 1.2.1 The terminology (including definitions of terms) is not in line or consistent with relevant EU legislation
- 1.2.2 The Foreword or the introduction contains inappropriate information not belonging there or misleads document users on its role and scope as a harmonised standard (e.g. contains requirements, legal or technical interpretations, information outside of the scope of a document)
- 1.2.3 The Scope covers products not considered by the relevant legal requirements of EU legislation or standardisation request and organisation/subdivision of technical content or Annex Z mislead users of a document on its support on EU legislation

HAS platform

- ▶ WHERE TO FIND
 - ▶ LIVELINK 'HAS PLATFORM'

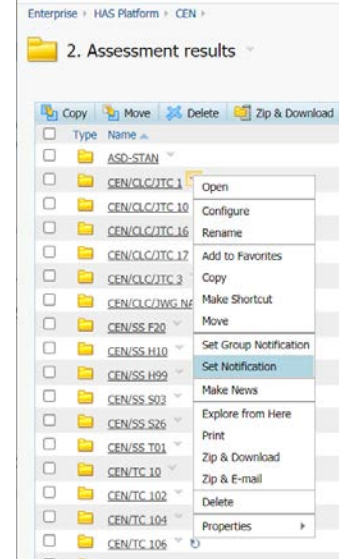


Download documents to be assessed and upload assessment results

HAS platform - Notifications

Set personal notifications via Livelink:


- ▶ Click on ▾ of the folder you are interested to receive notifications for and choose 'Set Notification'
- ▶ Select the recurrence of the notification: 'Hourly', 'Mid-day' or 'Weekly' and click submit
- ▶ Repeat for each folder you wish to receive notifications



Item: 1. To be assessed	
Notify Mail Projex when...	
An Item is added	Hourly Report ▾
An Item's status changes	Hourly Report ▾
A Version is added	Hourly Report ▾
A Version's status changes	Hourly Report ▾
A Compound Document Release or Revision is added	<<None>> Hourly Report Mid Day Report Weekly Report
A Topic is added	<<None>> ▾
A Reply is added	<<None>> ▾
A News Item is added	<<None>> ▾
<input type="button" value="Submit"/> <input type="button" value="Reset"/>	

FWD HAS assessment

Assessments: DRAFTING STAGE (indicative)

- ▶ TC secretary submits to CCMC the first working draft (FWD)
 - ▶ Transmission notice
 - ▶ CCMC Project Manager submits request to EY
 - ▶ First draft Annex Z 
 - ▶ For parallel work: CD-text

- ▶ Assessment report available on LIVELINK

- ▶ Lack of compliance → possible meeting

Electronic Transmission Notice		
TC Name		[provide TC name]
TC Title		[provide TC title]
Secretariat:	[NC]	[provide TC Secretary name and email address]
		[In case WG Convenor and project leader should receive a copy of the draft for TC proofing after Formal Vote, provide name(s) and email address(es)]

All documents submitted to CCMC shall comply with the CEN-CENELEC Internal Regulations - Part 3, "Rules for the structure and drafting of CEN-CENELEC Publications"

Reference Number:
Work Item Number:
Title:
Sending date:


Deliverable	EN <input type="checkbox"/>	HD <input type="checkbox"/>	Amdt <input type="checkbox"/>	TS <input type="checkbox"/>	TR <input type="checkbox"/>	AC <input type="checkbox"/>
Milestone	1 st Working Draft <input type="checkbox"/>	draft for ENQ <input type="checkbox"/>	draft for FV <input type="checkbox"/>	2nd ENQ <input type="checkbox"/> [provide TC decision, number, and date]	2nd FV <input type="checkbox"/> [provide BT decision, number, and date]	TS/TR vote <input type="checkbox"/>
	Publication <input type="checkbox"/> [In case of decision to skip FV following ENQ, provide TC decision, number, and date]					

GENERAL				
The text is sent in the following Reference language version in PDF and revisable Word format (only one Reference language permitted).				
	ENGLISH	FRENCH	GERMAN	Comments
Provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reference version	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
WORD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PDF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

TO BE FILLED IN IN CASE OF HARMONIZED STANDARD ONLY					
Standardization request	Related Directive/policy	New Approach OJEU citation	Assessment required by		
			HAS	EC	Other
[SREQ_1]	[DIR_1]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]
[SREQ_2]	[DIR_2]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]
[SREQ_3]	[DIR_3]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> [specify method]

TO BE FILLED IN IN CASE THIS IS A 1 st WORKING DOCUMENT:
<input type="checkbox"/> document is to be submitted to HAS Consultant for indicative assessment

Assessments: ENQUIRY STAGE

- ▶ Technical Body secretary submits prEN for ENQ (homegrown)
 - ▶ Annex Z
 - ▶ Checklist for hENs 
 - ▶ CCMC editor requests assessment at start translation
 - ▶ Assessment report available on LIVELINK
- ▶ 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

Assessments: FORMAL VOTE stage

- ▶ Technical Body secretary submits FprEN for FV (homegrown)
 - ▶ Annex Z
 - ▶ Checklist for hENs NEW
 - ▶ ENQ HAS assessment report → last column 'observations of the secretariat' completed to indicate how consultant comments have been addressed

MB/NC ¹	Line number [¶] (e.g. 17)	Clause/Subclause [¶] (e.g. 3.1)	Paragraph/Figure/Table [¶] (e.g. Table 1)	Type of comment ²	Comment [¶]	Proposed change [¶]	Observations of the secretariat [¶]
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: 7.2.2 Noise emission measurement This subclause of ISO 19085-1:2017 applies with the following additions.

- ▶ CCMC editor requests assessment at start translation
- ▶ Assessment report available on LIVELINK

Homegrowns

Decision BT C045/2018 and D159/C071, in case of a 'Lack of Compliance' at FV stage:

- ▶ **FV is suspended for maximum 12 weeks** after the reception of the assessment
- ▶ Technical Body Secretariat and BT member/PD of the NSB/NC holding the secretariat shall be informed
- ▶ Technical Body to decide on the way forward within 7 weeks

TCs to follow the procedure:

- 1) TC prepares the following documents:
 - a) **HAS Assessment report with the last column** 'Observations of the secretariat' **filled** to indicate how the TC is addressing the comments from consultant
 - b) **Re-worked draft in track changes** showing the changes made by TC in comparison with the version of FV draft which received a Lack of Compliance assessment
- 2) TC organises a meeting with HAS consultant → **highly recommended**
- 3) Prior to the meeting: TC provides to consultant the documents as listed in 1)
- 4) TC records outcome of meeting and asks Consultant for feedback: consultant's comments were sufficiently addressed in the revised text of hEN?
 - ▶ Feedback: email or at meeting

5) Following outcome of meeting/interaction with consultant, TC agrees on one of the following actions:

- ▶ **Revision of FprEN to resolve non-compliance assessment:**
 - ▶ TC secretary submits revised draft to CCMC for FV together with supporting documents → **HAS assessment resolved**
 - ▶ If FV is positive → hEN is offered to EC for OJEU citation

- ▶ **Adaptation of Annex Z (no additional changes to FprEN):**
 - ▶ TC secretary submits FprEN with revised Annex Z to CCMC for FV
 - ▶ If FV is positive → hEN is offered to EC for OJEU citation
 - ▶ **Exceptionally: PUB HAS assessment** could be requested in **limited cases** (final check Annex Z) → If lack of compliance assessment, still possible to revise Annex Z via BT for approval

5) As outcome of meeting/interaction with consultant, TC agrees on one of the following actions:

▶ **Temporary de-harmonization:**

- ▶ TC concludes that harmonization is **temporarily** not possible
- ▶ TC takes a decision to request BT to remove Annex Z and link to legislation
- ▶ If BT approves → adapted standard can proceed to FV
- ▶ CCMC Project Manager will inform EC about de-harmonization
- ▶ TC to initiate amendment/revision to resolve non-compliance assessment → to be published as harmonized standard

5) As outcome of meeting/interaction with consultant, TC agrees on one of the following actions:

▶ **Permanent de-harmonization:**

- ▶ TC concludes that harmonization is not possible (**permanent**)
- ▶ TC takes a decision to request BT to remove Annex Z and link to legislation
- ▶ If BT approves → adapted standard can proceed to FV
- ▶ CCMC Project Manager will inform EC about de-harmonization

5) As outcome of meeting/interaction with consultant, TC agrees on one of the following actions:

▶ **Abandon the work:**

- ▶ TC concludes that it is not possible to progress draft standard to FV → due to significant comments from HAS consultant
- ▶ TC takes a decision to request BT to discontinue the work and abandon WI
- ▶ If BT approves → WI is abandoned
- ▶ TC could initiate amendment/revision to resolve lack of compliance assessment → to be published as harmonized standard

Assessments: Review

On justified disagreement of Technical Body

- ▶ Technical Body Secretary sends 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)

How to request meetings

- ▶ Technical Bodies to request meetings via EY [link](#) for:
 - ▶ Face-to-face meetings
 - ▶ Virtual meetings (more than 4 hours)
- ▶ Technical Bodies to contact directly HAS consultant for web-meetings less than 4 hours

HAS Meeting Requests

Page 1 of 1

NON ANONYMOUS

This survey has been designed to capture user data. This means that when EY has sent you a link to this survey, your responses will be combined with your email address and other demographic information in order for EY to be able to create specific and individualized reports on the survey results. Furthermore, EY will collect additional data, such as your IP address and the time you filed your answers. Ernst & Young will be able to view all individual responses. EY will use a limited amount of cookies to store information on your computer, but only to the extent this is essential for the survey to operate. If you decide not to complete this survey or if you are inactive for more than 20 minutes, these cookies will be automatically deleted. To find out more about the cookies we use, see our [our cookie notice](#).

Dear All,

This page is aimed at providing a quicker and more efficient way to request meeting attendance from the HAS Consultants. As such, please try to be as specific as possible when answering the questions below and especially those regarding the scope of the meeting. It is also particularly important to fill-in the requestor contact details correctly so that our team is able to contact you as soon as your request has been approved or in case something is unclear.

Furthermore, please note that all requests will preferably be issued at least four weeks before the meeting date and that these must come from either the EC service or the ESOs. As such, requests issued from the HAS consultant will not be accepted.

Finally, please note that such a formal meeting request issued through this platform is always needed each time the presence of a HAS Consultant is required for **any face-to-face meeting (regardless of the duration) or for a virtual meeting that extends more than half-day (4 hours)**. Meeting requests are not needed for written exchanges (requiring clarifications by e-mail directly to the consultant) or for phone calls and short video calls (less than 4 hours). We encourage virtual participation as much as possible to make effective usage of the Consultant's available time.

Thank you for your understanding.


The HAS Support Team

1. **Requestor name***
2. **Requestor e-mail address**
Any communication related to the request will be sent to this e-mail address.*
3. **Requestor's phone number**
Please insert below your phone number so that our team can reach you out quickly, if necessary.
4. **Requestor entity**
Please specify which entity you are from.*
5. **Requestor position within the entity**
Please use the space below to mention your position, i.e. CCMC Project Manager, CEN TC member, EC Desk Officer, etc.*
6. **Requestor TC or sector unit**
Please mention below which specific TC or unit sector you cover, i.e. CEN/TC10, DG GROW/C.1, etc.
7. **Requestor sector**
Please select one of the options below.*

Following practices go beyond the tasks of HAS Consultants and are **not allowed**:



1. To receive (revised) draft standards directly by TCs and assess the modified documents outside the formal assessment process
2. To support the TC in drafting elements included in the standards
3. To provide suggestions and try to find possible solutions for issues of the draft standards, and more in general participate in consensus-building activities within the TC
4. To provide general guidance on the Regulations without prior alignment with the relevant EC services or to address matters not related to clarifying comments of specific work items previously assessed
5. To accept requests from Technical Bodies for meetings after performing a “Final verification”

- ▶ Request first working draft (FWD) HAS assessment 
- ▶ Exchange with the HAS consultant has much as possible → organise meetings
- ▶ Prepare documentation for meetings
 - 1) HAS assessment report with TC remarks
 - 2) revised standard in track changes
- ▶ Normally, 'Compliant' assessment required for publication → some exceptions are possible under certain conditions



European Standardization Organizations

Thank you!

Nuno Pargana, Account Manager Manufacturing

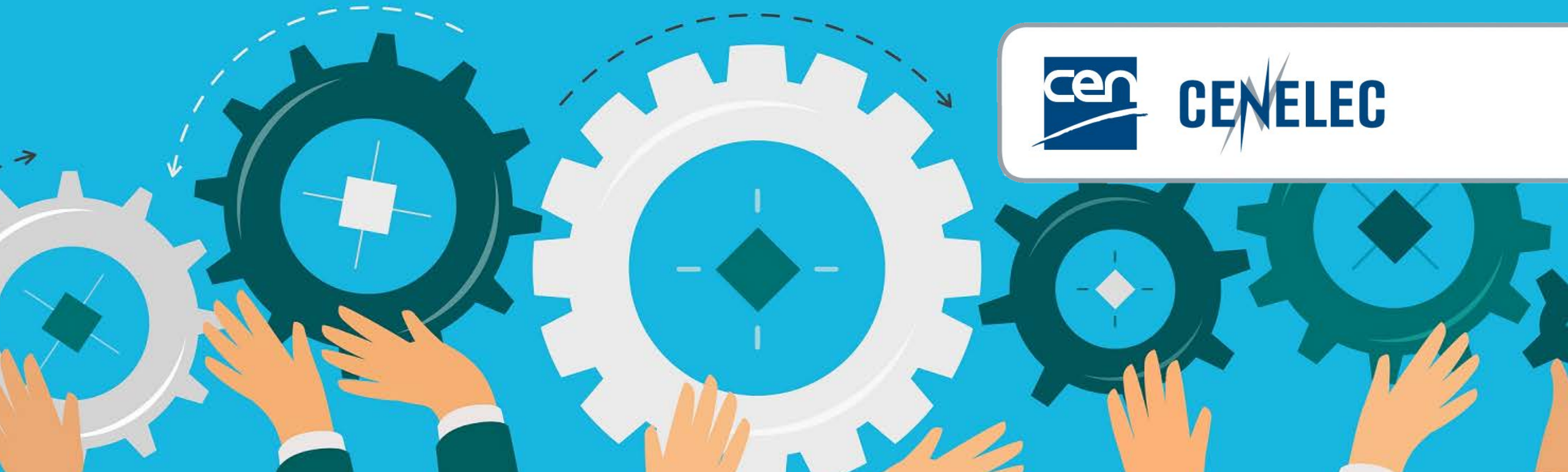
npargana@cencenelec.eu





European Standardization Organizations

Let's have a small break!



European Standardization Organizations

Elaboration of harmonized standards

Thierry Legrand, Account Manager Mobility

Nuno Pargana, Account Manager Manufacturing



- ▶ **Normative references** (all sectors)
 - ▶ Undated normative references (without justification)
 - ▶ Outdated normative references
- ▶ **Annex ZA/ZZ** (all sectors)
 - ▶ Incorrect use of template
 - ▶ Incorrect link between Essential requirements of directive and clauses of hENs
 - ▶ Lack of granularity
 - ▶ Inclusion of clauses not linked with Essential requirements
- ▶ **Other reasons** (few cases)
 - ▶ Out of scope of EU Directive/Standardization request
 - ▶ Repeating or wrong use of EU legislation terminology

Drafter checklist



Annex A (informative)

Checklist for writers and editors of documents

The following checklist is a tool to help writers and editors of documents.

Task	Assessment	Done <input checked="" type="checkbox"/>	Comments
Structure	Check table of contents: Is the top-level structure logical? Is the subdivision consistent?		
	Hanging paragraphs: Check for and remove any hanging paragraphs.		
Use of plain language	Is the text clear and concise?		
	Are the sentences short? (check punctuation)		
Title	Is the title organized going from the more general to the more particular?		
	Does the title unintentionally limit the scope of the document?		
	Is it as clear and concise as possible?		
	Make sure that the title does not contain more than three elements. If there are several parts, are the titles aligned?		
Foreword	Is the document a revision? If so, insert a revision statement including any amendments and technical corrigenda and a list of changes with respect to previous edition. Are there any other organizations involved in the drafting that should be mentioned?		
	Is it purely informative?		
Introduction	Does it describe the content or give information on why the document is needed?		
	Does it describe what the document does?		
	Does it state where it is applicable? Does it only contain statements of fact?		
Normative references	Normative references clause: are all the references cited in the text actually normative?		
	Are the references dated or undated?		
	Are the references used ISO and IEC standards? If not, do suitable ISO and IEC standards exist which could be used instead?		
	Are the normative references publicly available? References cited in a normative manner in the text: are all such references listed in Clause 2?		
Terms and definitions	Are the terms listed used in the document?		
	Do suitable terms exist in the terminology databases? - http://www.electropedia.org/ - http://www.iso.org/obp		
	Are the definitions correctly drafted?		

Internal Regulations Pt 3 – Annex A

All potential issues & drafting requirements covered

Follows the structure of a European Standard

Task	Assessment	Done <input checked="" type="checkbox"/>	Comments
Figures	Does each figure have a concise title?		
	Is each figure numbered correctly?		
	Is there a key if necessary?		
	Are all figures cross-referenced in the text?		
Graphical symbols	Are symbols used taken from the ISO and IEC databases? If not, contact IEC TC 3, IEC SC 3C and ISO/TC 145 in order to register a standardized symbol.		
	Does each table have a concise title?		
Tables	Is each table numbered correctly?		
	Are all tables cross-referenced in the text?		
	Is there a reference to each annex in the main part of the text? Is their status (normative or informative) correct? Is this made clear in the main part of the text?		
Annexes	Is it formatted consistently?		
	Are all the entries correct and complete?		
	Are any of them normative references that should be listed in Clause 2? Are any of the listed documents duplicated in Clause 2?		
Bibliography	Make sure that "shall", "should" or "may" are not used in the foreword, Scope or notes. Make sure that "shall", is not used in the Introduction. Are "may" and "can" used correctly?		
	Is "must" used anywhere in the document? Is "must" used correctly to mean external constraints?		
	Make sure that no requirements specifying compliance with national/legal regulations are included.		
	Copyrights Trademarks Patents		
Potential legal problems	Are there potential conformity assessment issues?		
Conformity assessment	Are all cross-references correct?		
Cross-references	Are symbols for variable quantities correctly formatted in the text and mathematical formulae? Is a comma on the line used as the decimal sign?		
Common problems	Are symbols for variable quantities correctly formatted in the text and mathematical formulae? Is a comma on the line used as the decimal sign?		
	Other issues		

Preparation of New Work Item

18. Related standardization request(s) (formerly mandate):		
<input type="checkbox"/> No		
<input type="checkbox"/> Yes <i>(please specify):</i>		
19. Related directive(s)		
<input type="checkbox"/> No		
<input type="checkbox"/> Yes	Directive reference	Candidate for citation in Official Journal?
		<input type="checkbox"/> No <input type="checkbox"/> Yes
		<input type="checkbox"/> No <input type="checkbox"/> Yes

Page 4 of 5

20. Relation to other legislation or established public policy.
<input type="checkbox"/> No
<input type="checkbox"/> Yes
<i>Please specify which legislation or established public policy is/are in relation with the proposed project:</i>

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

No

X Yes (please specify): M/396 Machinery Directive (MD)

M/511 Low Voltage Directive (LVD) see note 1

Note 1: This WI is not currently part of the LVD Sreq !!

19. Related directive(s)

No

X Yes Directive reference Candidate for citation in Official Journal?

2006/42/EC X Yes No

2014/35/EU X Yes No

20. Relation to other legislation or established public policy.

No

X Yes

Please specify which legislation or established public policy is/are in relation with the proposed project:

2014/24/EU | Public Procurement

Unforeseen Rev /Amdt of harmonized std falling in context of a Sreq

Please inform your CCMC contact person.

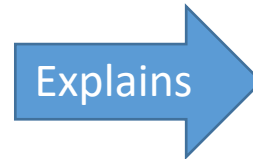
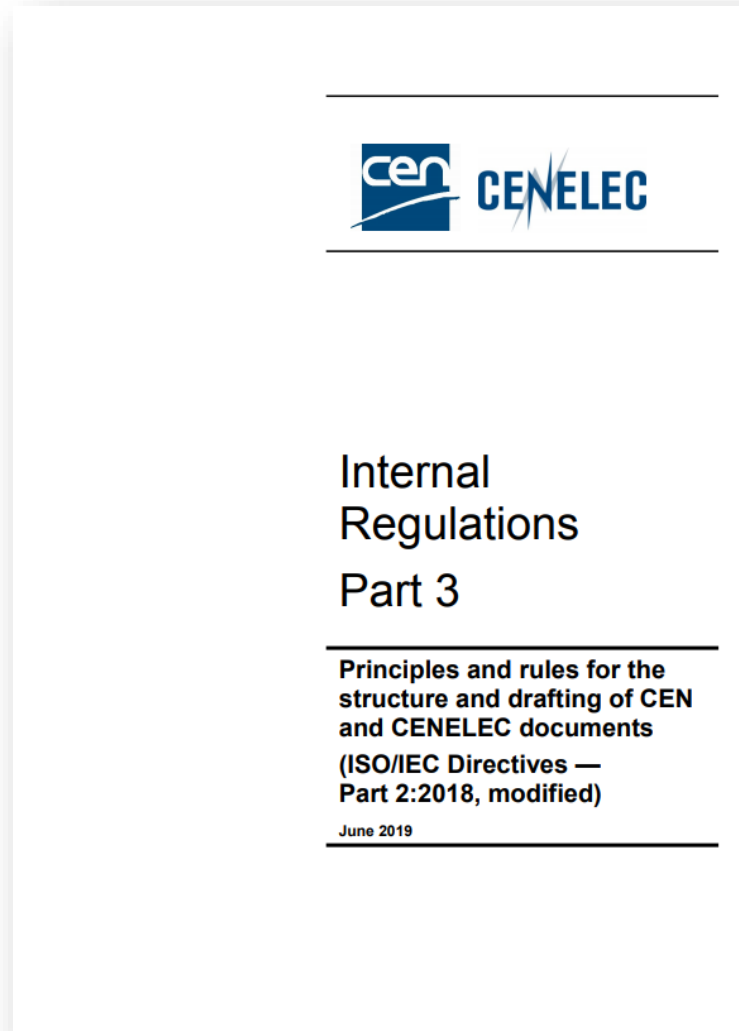
In the future, if an item is not part of a Sreq Work Programme:

- ▶ The draft standard will not be assessed by the HAS system
- ▶ The published standard will not be referred in the OJEU

European foreword

- ▶ This document (prEN XXXX:XXXX) has been prepared by Technical Committee CEN(ELEC)/TC XXX “Title”, the secretariat of which is held by XXX.
- ▶ This document is currently submitted to the CEN/CENELEC Enquiry.
- ▶ This document will supersede EN XXXX:XXXX.
- ▶ In comparison with the previous edition, the following technical modifications have been made:...
- ▶ This document has been prepared under a standardization request given to CEN/CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).
- ▶ For relationship with EU Directive(s), see informative Annex ZA/ZZ, which is an integral part of this document.

- ▶ The scope of the harmonized standard shall be concise and clear and worded as a series of statements of facts.
- ▶ In line with CEN-CENELEC Internal Regulation Part 3, the scope shall not include requirements, permissions or recommendations.
- ▶ The scope shall be consistent regarding content covered by the standard.



□ Clause 10

- 10.1 Purpose or rationale
- 10.2 Permitted referenced documents
- 10.3 Presentation of references
- 10.4 Undated references
- 10.5 Dated references
- 10.6 References in a document to itself

□ General information

- is mandatory (clause 2)
- lists the normative references used in the standard for the convenience of the standard user (how they should be applied is described in the text of standard)
- the clause is informative
- Information on how these references apply is found in the place where they are cited in the document
- the clause starts with the following

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- informative references should NOT be listed in this clause (they can be listed in bibliography)

□ Undated references may be used under below condition:

- only to a complete document;
AND
- if it will be possible to use all future changes of the referenced document for the purposes of the referring document. Because, for undated references, the latest edition of the referenced document (including any amendments) applies
AND
- when it is understood that the reference will include all amendments to and revisions of the referenced document.



Special
attention to
hEN!

□ Dated references are:

- references to a specific edition, indicated by the date of publication
- OR**
- references to a specific enquiry or final draft¹

□ For dated references, only the edition cited applies

□ TC role is very important!

- if there a new edition or amendment, TC should review the dated references and assess if the document should be updated.



Special attention to hEN!

⁽¹⁾ with a dash together with a footnote, such as "Under preparation"

Dated vs Undated, example:

Undated

Listed:

- IEC 60335 (all parts), Household and similar electrical appliances – Safety (Reference to all parts)
- IEC 60335-1, Household and similar electrical appliances – Safety – Part 1: General requirements (Reference to a single part)

In the text:

- “ ... use the methods specified in ISO 128-20 and ISO 80000-1 ... ”;
- “ ... IEC 60417 shall be used... ”.

Dated

Listed:

- IEC 62271-1:2007, High-voltage switchgear and controlgear – Part 1: Common specifications

In the text:

- “ ...as specified in IEC 64321-4:1996, Table 1... ”;
- “ ... according to IEC 62271-1:2007... ”.

European Commission requirements

- ❑ Normative references are integral part of the standard
- ❑ Standards are part of a legal system
- ❑ Presumption of Conformity: legal effect, given by EC
- ❑ What EC requires?

- Requirement from EC very aligned with IR part 3
- Since the legal effect of harmonized standard is given by EC (beginning & end), EC requires **stable normative references**

hence,



- Dating of Normative References
- Documents must be publicly available
- TC should actively assess & validate all the references when a document is revised
- To use minimum number of references
- For undated references, evaluate the impact of evolution → Risk of **loss of presumption of conformity**
- Normative references do not need to be harmonized

Dated References



▲ **Default solution**

Parallel work with ISO and IEC

□ When adopting IEC standard

- Normative references to international publications with their corresponding European publications (For CENELEC only) are listed under **Annex ZA**

□ Annex ZA :

- It's normative
- Has specific template
- It replaces the reference in the body of the text
- Comes at the end of the standard (not clause 2)
- Basic rule: if not dated in IEC version → should not be dated in EN IEC version since it is pure adoption with no modification

Template

"Annex Z ...
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
--------------------	-------------	--------------	--------------	-------------

Normative references // ISO



□ When adopting an ISO standard

- The same EU requirement apply
- Dated normative references are the default solution
- Listed in Clause 2 (no CLC Annex ZA equivalent)

HAS consultants' requests vs. CEN-CLC IR3

To establish common understanding on the:

- Request to date a complete series of standards
- Request to refer in the Annex ZA to a standard that is not normatively referenced in the EN IEC text
- Request to provide complete Annex ZA in the frame of an amendment (covering main + amendment)

Common understanding on Normative References in hEN

□ Normative References in hEN

- Both dated and undated references can be used in harmonized standards
- Whenever TC considers the use of non-dated normative references, they shall check with the HAS consultant/European Commission
- If deemed necessary, the TC would have to carry out a risk assessment/justification on the use of undated normative references
- In case an undated reference is included, the EC may consider a notice in the OJEU (informing that undated references are included)
- CEN and CENELEC to strengthen the support to TC that develop harmonized standards, to comply with the drafting rules and the EC requirements
- CEN-CENELEC IR3 are an essential tool!
- Ensure communication on the matter with HAS consultants

- ▶ The terminology used in the standard, including definitions of terms in Clause 3, shall be consistent with the relevant EU legislation.
- ▶ The technical content of the document shall not:
 - ▶ contain requirements that contradict relevant EU legislation (e.g., fails to specify 'technical solutions', allows users of a document to decide on the specification);
 - ▶ repeat legal requirements as part of its normative requirements.

Risk reduction

- ▶ If a harmonized product standard deals with safety aspects, the relevant hazards must be identified and the risks reduced.

Neutrality principle

- ▶ The draft standard must respect the neutrality principle.
- ▶ The standard shall not contain clauses imposing requirements or obligations on or between certain economic operators (e.g. requirements are set to an economic operator and its competence or resources instead of to product design and product properties).
- ▶ The standard shall not contain clauses imposing first, second- or third-party assessment conformity.

Annex ZA (informative)

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

All harmonised standards must include an **Annex ZA**, **ZZ (for CLC)** 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	

- Not following template – see relevant template in CEN or CLC BOSS
- Lack of granularity (e.g. § 4, 5, 6)
- Wrong match between clauses of EN and ER
- Including elements not relevant for the ER linked
- Clauses of other standards mentioned in the Annex ZA/ZZ
- Not covering other parts of standards

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

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](#)

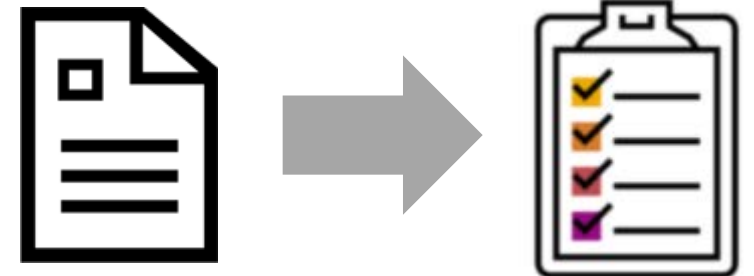
- ▶ Last months: increase outcome HAS assessment 'Lack of compliance'
- ▶ Need to support Technical Bodies to increase HAS assessment 'Compliant'



- ▶ **Technical Boards approved checklist to assist Technical Bodies in drafting harmonized standards** (decision BT C089/2021 and D168/C108)

Checklist for hENs: main principles

- 1) When drafting homegrown hENs, harmonized standards under VA (CEN lead) or European Common modifications (CENELEC) → **Technical Bodies shall check their compliance against a dedicated checklist**
- 2) TC secretary in CEN and Technical body secretary/ Reporting Secretariat in CENELEC → **ensure checklist is filled out and submitted to CCMC with the draft hEN and supporting documents** (where relevant)
- 3) During the ENQ and FV procedures: **CCMC will reject, as of 2021-10-01, the submission of draft hEN if the completed checklist and relevant documents were not submitted**



- ▶ **Checklist:** horizontal aspects to be considered by TCs when **drafting hEN in view of OJEU citation**
- ▶ Recommended until 2021-09-30 → **mandatory afterwards**
- ▶ Horizontal checklist applies to all sectors
 - ▶ Specific checklist for construction under preparation
- ▶ Checklist shall be completed before dispatching draft standard for:
 - ▶ First working draft stage
 - ▶ Enquiry
 - ▶ Formal Vote
 - ▶ Following lack of compliance assessment at FV stage (e.g. resubmission)
- ▶ Strongly recommended the checklist for drafting of hEN under VA and FA (with ISO or IEC lead)

Checklist for hENs

► CEN and CENELEC BOSS pages on drafting hENs under finalization

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?</p> <p>Is this reflected in Projex-online database?</p> <p><i>NB: This information is normally already provided in the NWIP form.</i></p> <p><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 <u>all</u> comments from the HAS Consultant(s)?</p> <p><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?</p> <p><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></p> <p><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.”?</p> <p><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?</p> <p>Are the title, <u>scope</u> and annex Z consistent regarding exclusion / content covered by the standard?</p> <p><i>NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation.</i></p> <p><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”).</p> <p><i>NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i></p>	<input type="checkbox"/>
	Are the normative references dated in Clause 2 and in all clauses of the draft standard?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Checklist for hENs: ENQ/FV process (CEN)

WG

- ▶ WG drafts hENs
- ▶ WG Qualified support checks that the draft hEN fulfils requirements to be cited
- ▶ WG Qualified support ensures that checklist is filled out
- ▶ WG Qualified support/convenor submits to TC secretary:
 - 1) **Draft hEN**
 - 2) **Checklist filled out**
 - 3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

TC secretary

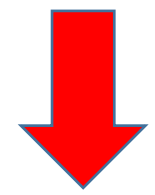
- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?



ENQ/FV procedure could start

Checklist not submitted?



CCMC will reject hEN submission

CEN: **matrix responsibilities** to be followed (decision BT C081/2018)

Checklist for hENs: ENQ/FV process (CENELEC)



WG

- ▶ WG drafts hENs
- ▶ WG ensures that following docs are submitted to TC secretary:
 - 1) **Draft hEN**
 - 2) **Checklist filled out**
 - 3) **ENQ HAS assessment report with last column filled on how consultant comments were addressed** (applicable for FV only)

TC secretary

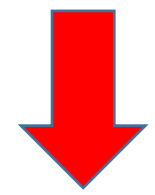
- ▶ Checks that checklist is filled out
- ▶ Submits the draft hEN and checklist to CCMC for ENQ/FV procedure

hEN + checklist submitted?



ENQ/FV procedure could start

Checklist not submitted?



CCMC will reject hEN submission

CENELEC: **matrix of responsibilities** under discussion



European Standardization Organizations

Thank you!

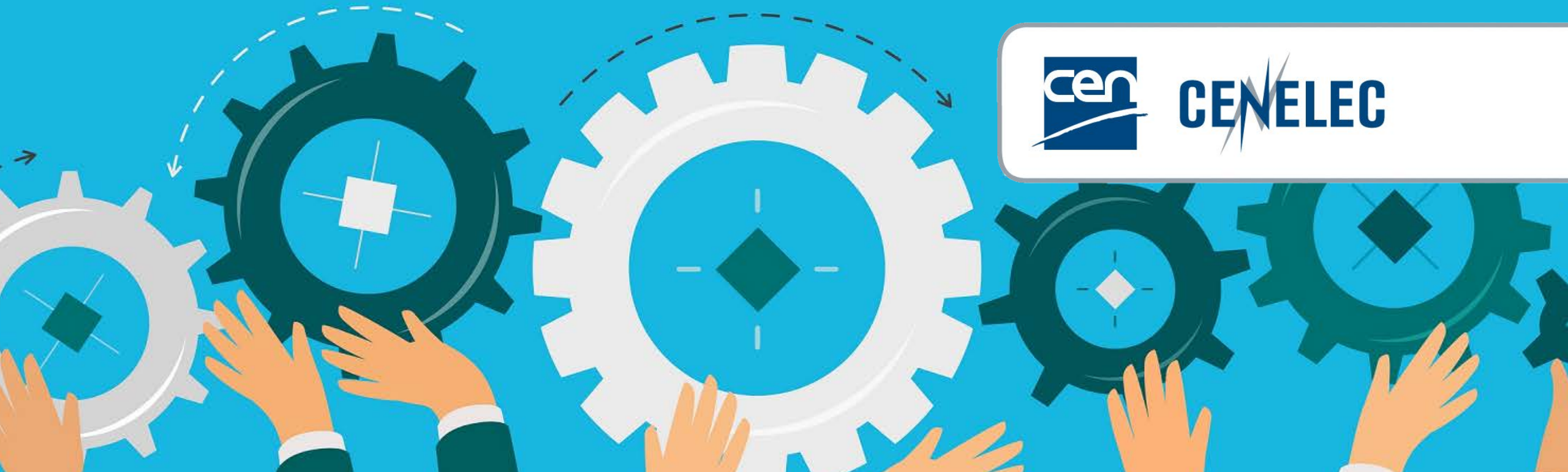
Thierry Legrand, Account Manager Mobility

tlegrand@cencenelec.eu

Nuno Pargana, Account Manager Manufacturing

npargana@cencenelec.eu





European Standardization Organizations

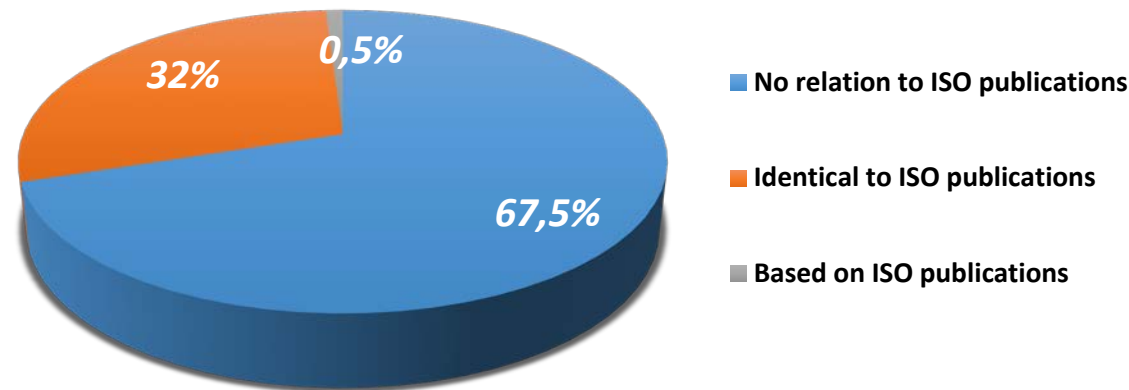
Drafting hENs in the international context: Vienna Agreement (CEN/ISO) & Frankfurt Agreement (CENELEC/IEC)

Constant Kohler, Account Manager Electrotechnology



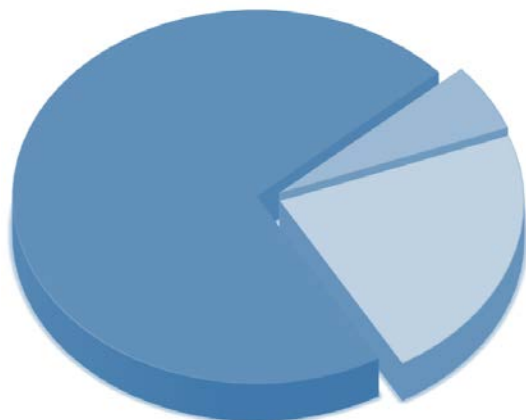
Vienna Agreement (VA) - Facts and Figures

What?	When?	Why?
<ul style="list-style-type: none">Formal agreement on technical cooperation between ISO and CEN	<ul style="list-style-type: none">1991 - Signature2001 'Codified version'2016 'Guidelines on implementation'	<ul style="list-style-type: none">To avoid duplication of work at International and European levels



Frankfurt Agreement (FA) - Facts and Figures

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



- 72% Identical to IEC publications
- 6% Based on IEC publications
- 22% No relation to IEC publication

Under the Vienna and Frankfurt Agreements

- The **same principles apply** – but with additional considerations to address the international standardization processes
- It requires **consensus-building** at European and international levels
- It requires **strong communication and coordination** between the European TC and the international TC (specific role for secretaries, convenors and TPM)

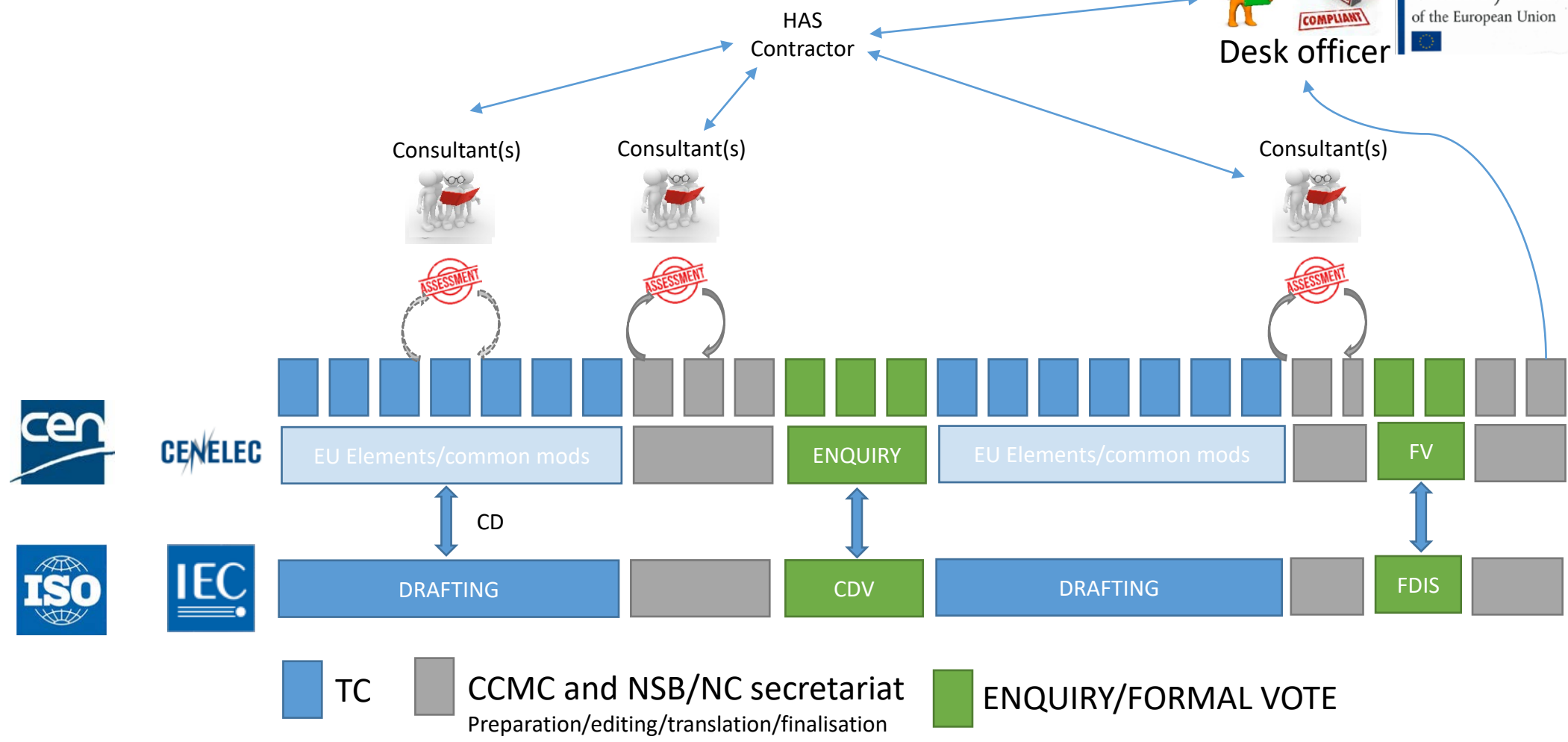


A same standard will apply worldwide and will provide presumption of conformity to European directives/regulations

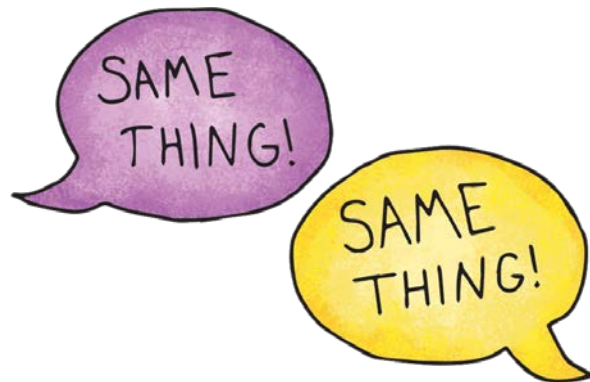
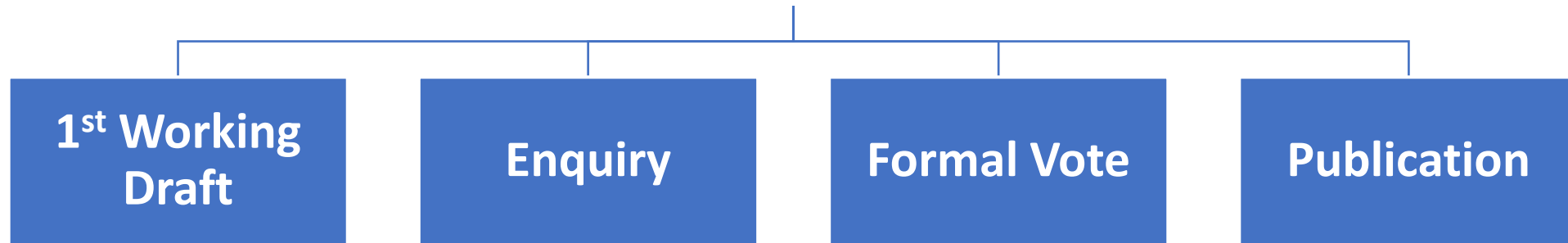
Standards development process



Official Journal
of the European Union



When can assessment be requested?



However, consider that in the case of ISO or IEC lead, the **international committee drafts, develops and progress the standard** – the specific European elements (e.g. Annex Z) need to be “attached” to the standard for (1) the parallel European standardization processes and for (2) the assessment requests...

Interaction with standards' development

Therefore, the following considerations apply in case of ISO or IEC lead:

- **The checklist does not have to be provided** by the European TC (but its use is recommended!), since the standard is being developed at international level – Further, the European TC does not decide when the standard will be submitted to the standardization procedures
- The assessment still needs to be requested before the start of the parallel Enquiry or parallel Formal Vote, however consider particular dimensions for ISO or IEC:
 - For parallel EN IEC, **the standard cannot be modified before the formal start of the Enquiry or Formal Vote** (e.g. the European TC cannot decide to suspend the launch of the Enquiry or Formal Vote to address the consultant's comments)
 - For parallel EN ISO, ISO will not start the vote until the results of the assessment are known – then, depending on the outcomes, ISO may decide to start the vote or not
- Resolving a non-compliant assessment at Formal Vote: the European TC cannot trigger (for instance) a second Formal Vote – CEN/ISO and CLC/IEC would not be aligned anymore – nonetheless the European TC can still work on the European annexes



What does not change!

- ▶ NWI: European TC evaluates the possibility to link the WI with a standardization request's work programme
- ▶ Request first working draft (FWD) HAS assessment
- ▶ Exchange with the HAS consultant as much as possible
- ▶ Prepare documentation for meetings (e.g. HAS assessment report with TC remarks)
- ▶ Normally, 'Compliant' assessment is required for CEN or CENELEC to proceed with the publication of the European Standard

100



In case the parallel EN/IS is not compliant, it does not mean that the standard is not good for the market... It simply means that the EN/IS has not met the specific European requirements for compliance:

- ✓ • Concise and clear **scope**
- ✓ • Objectively-verifiable **requirements** and **test methods** (e.g. avoid that a same clause addresses (for instance) safety, EMC and radio requirements)
- ✓ • **Normative references** must be dated
- ✓ • **Neutrality** principle: the standard shall not contain clauses imposing requirements or obligations on or between certain economic operators
- ✓ • Annex ZA (CEN) and Annex ZZ (CENELEC)
- ✓ • Comply with **sector specific rules...** see dedicated Webinars and Trainings

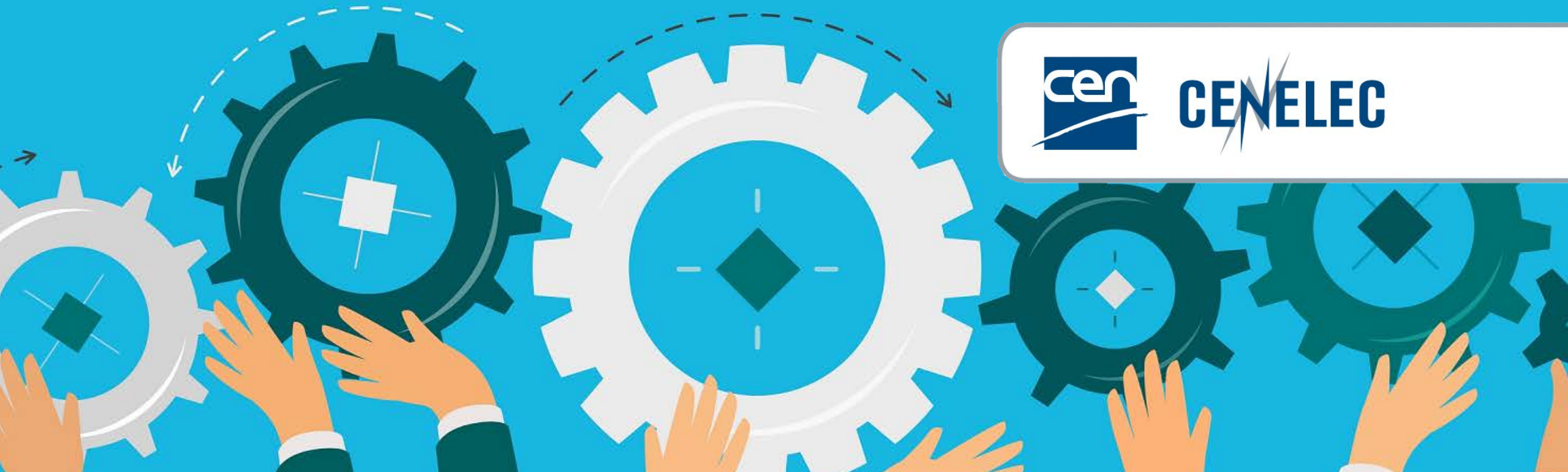


European Standardization Organizations

Thank you!

Constant Kohler, Account Manager Electrotechnology
ckohler@cencenelec.eu





European Standardization Organizations

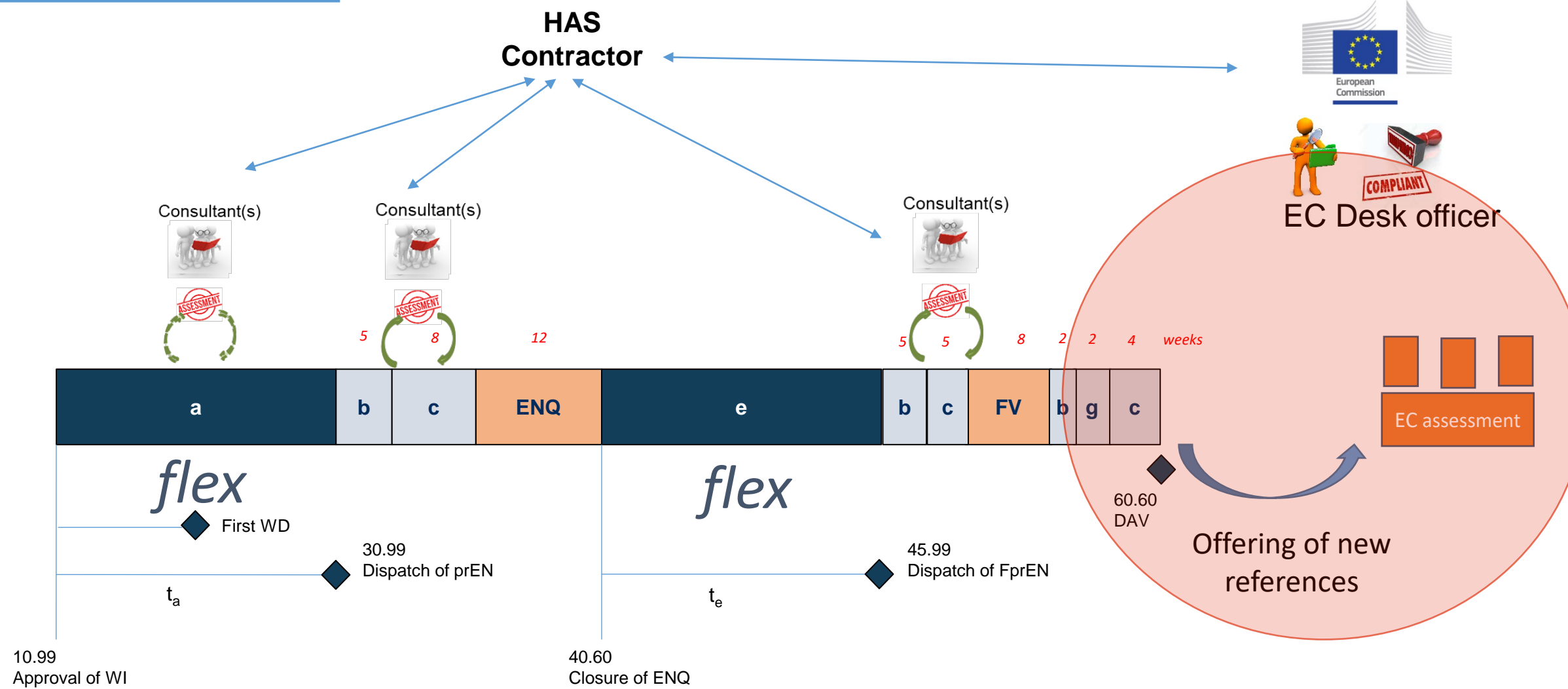
Citation of hENs in the OJEU

Goncalo Ascensao

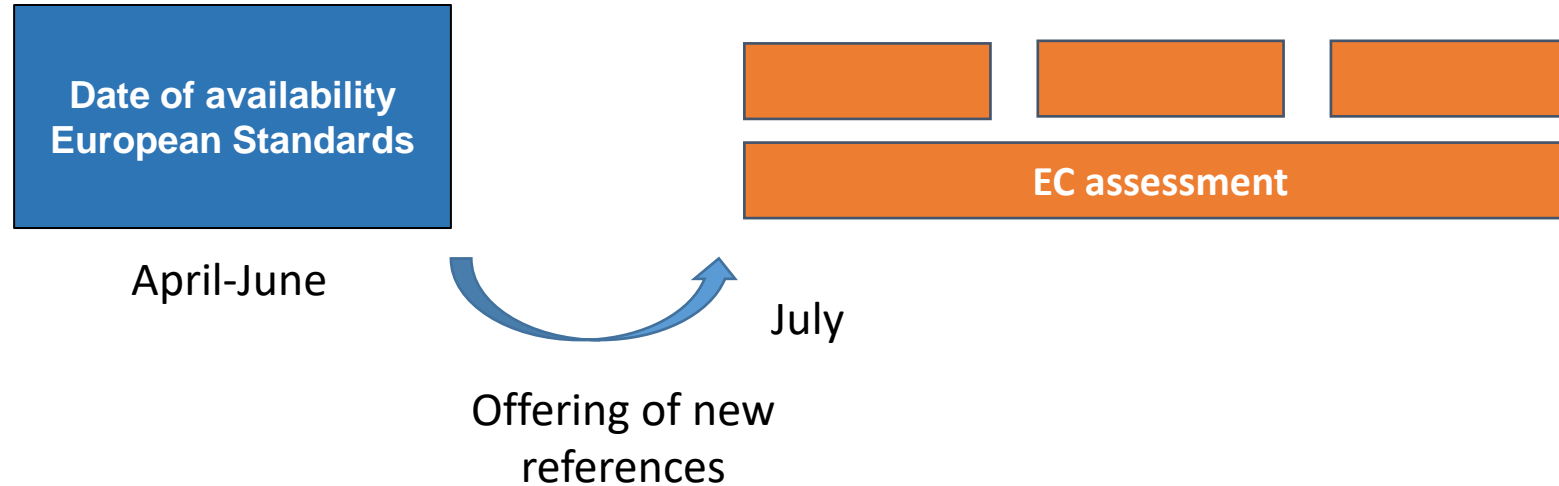
Account Manager - Digital Solutions



Citation of hENs in the OJEU – the process

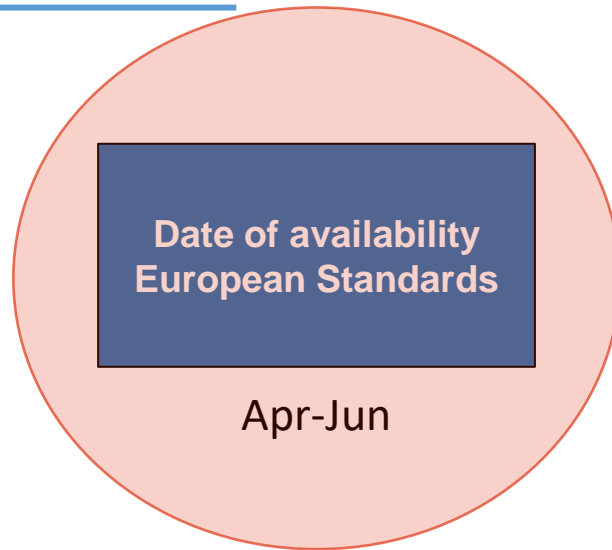


The process step by step



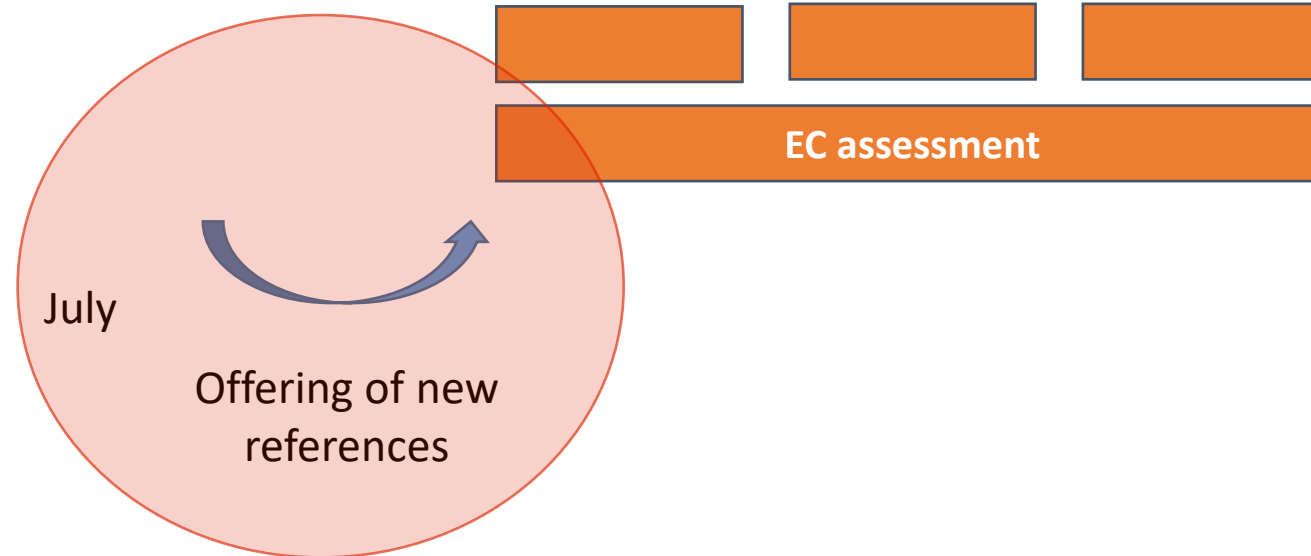
- ▶ Every Quarter CEN and CENELEC offer references to EC;
- ▶ e.g. DAV between April-June → offered in July

Before end of Quarter

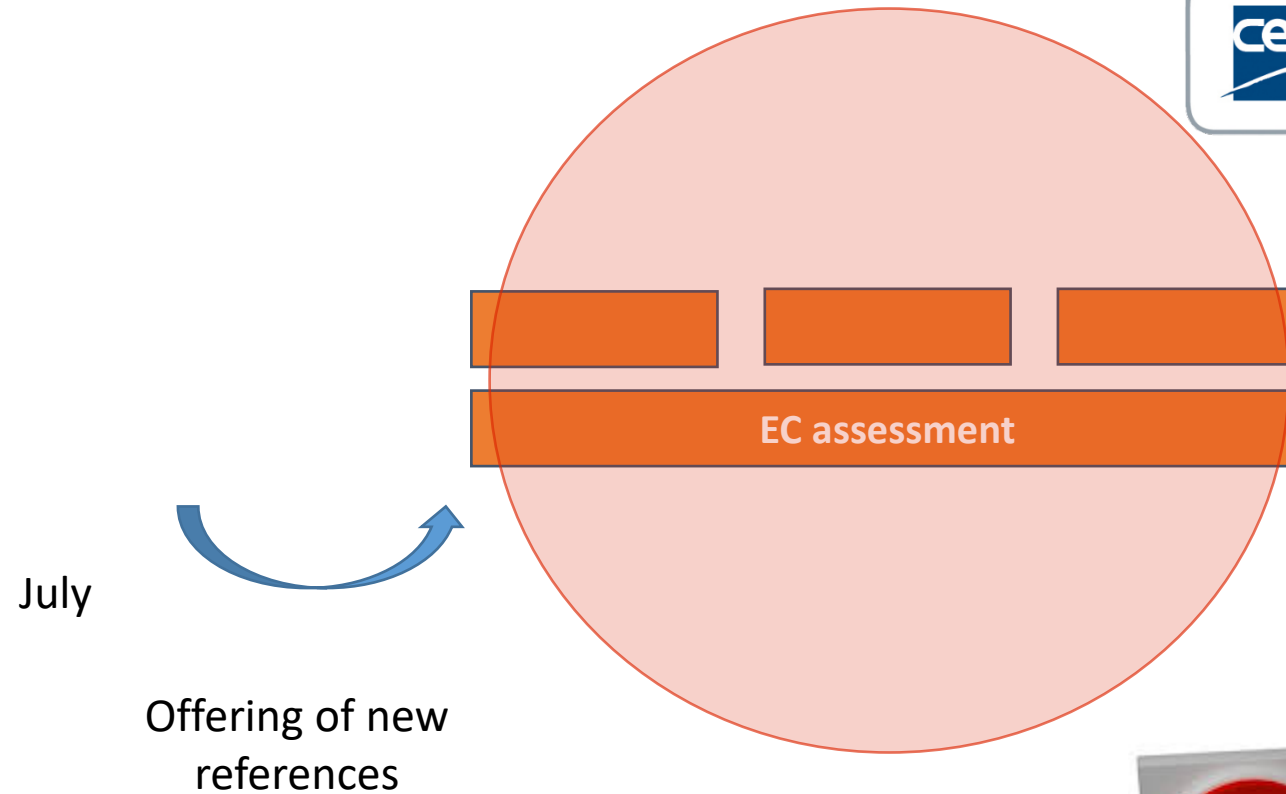


Quarter	Period
Q1	Jan-Mar
Q2	Apr-Jun
Q3	Jul-Sep
Q4	Oct-Dec

- ▶ CCMC identifies new references;
- ▶ Validation of compliance with HAS assessment (if relevant);
- ▶ Creation of the new lists to be offered (different Directives/Legislation);
- ▶ Pre-notification of references sent to EC;



- ▶ Lists which have been validated by CCMC;
- ▶ Formal letter sent to EC;
- ▶ References are provided to EC;



- ▶ 10 weeks deadline to provide feedback;
- ▶ Possible outcomes are:
 - ▶ Acceptance – leading to citation in OJEU
 - ▶ Rejection – reply to CEN and CENELEC



Citation in OJEU in the L series
info available in

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

- ▶ CEN and CENELEC are informed

Citation in OJEU in the L series – e.g. Low Voltage

22.6.2021

EN

Official Journal of the European Union

L 222/45

ANNEX I

Annex I to Implementing Decision (EU) 2019/1956 is amended as follows:

- (1) row 11 is deleted;
- (2) the following row 11a is inserted:

'11a.	EN 60335-2-85:2003 Household and similar electrical appliances – Safety -Part 2-85: Particular requirements for fabric steamers EN 60335-2-85:2003/A1:2008 EN 60335-2-85:2003/A11:2018 EN 60335-2-85:2003/A2:2020'
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Citation in OJEU in the L series – e.g. Toys

31.5.2021

EN


Official Journal of the European Union

L 190/99

ANNEX I

No	Reference of the standard									
1.	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties									
2.	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability									
3.	EN 71-3:2019 Safety of toys - Part 3: Migration of certain elements									
4.	EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities									
5.	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets									
6.	EN 71-7:2014+A3:2020 Safety of toys — Part 7: Finger paints — Requirements and test methods									
7.	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use									
8.	<p>EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances</p> <p>Informative note: The limit values in point a) of Table 2 of clause 4.2 of standard 'EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances' are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:</p> <table border="1"> <thead> <tr> <th>Substance</th> <th>Standard EN 71-12:2016</th> <th>Directive 2009/48/EC</th> </tr> </thead> <tbody> <tr> <td>N-nitrosamines</td> <td>0,01 mg/kg</td> <td>0,05 mg/kg</td> </tr> <tr> <td>N-nitrosatable</td> <td>0,1 mg/kg</td> <td>1 mg/kg</td> </tr> </tbody> </table>	Substance	Standard EN 71-12:2016	Directive 2009/48/EC	N-nitrosamines	0,01 mg/kg	0,05 mg/kg	N-nitrosatable	0,1 mg/kg	1 mg/kg
Substance	Standard EN 71-12:2016	Directive 2009/48/EC								
N-nitrosamines	0,01 mg/kg	0,05 mg/kg								
N-nitrosatable	0,1 mg/kg	1 mg/kg								

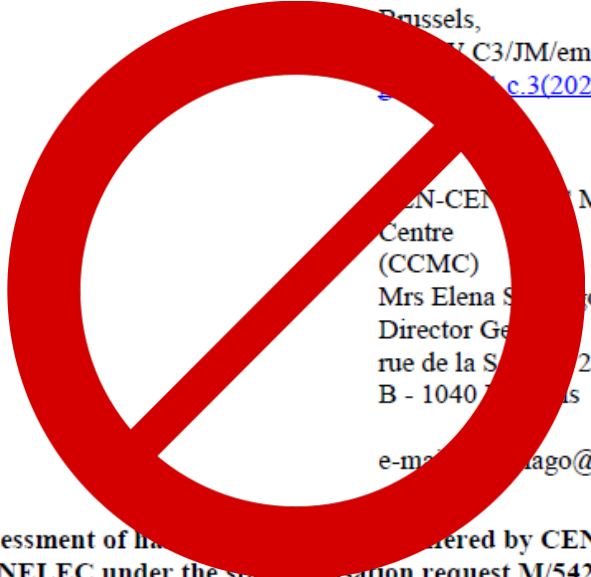
Rejection of citation

 Ref. Ares(2021)1761531 - 11/03/2021



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES
Industrial Transformation and Advanced Value Chains
The Director

Brussels,
C3/JM/em
[c.3\(2021\)1790929](#)



CEN-CENELEC Management
Centre
(CCMC)
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Director General
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B - 1040 Brussels
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Subject: Assessment of the standards developed by CEN and CENELEC under the standardisation request M/542, C(2015) 8736 final of 15.12.2015 in support of Directive 2013/53/EU related to recreational craft

Outcome of EC assessment

- ▶ EC letter with reasons is received;
- ▶ CCMC informs Technical Bodies;
- ▶ Follow-up actions are needed.

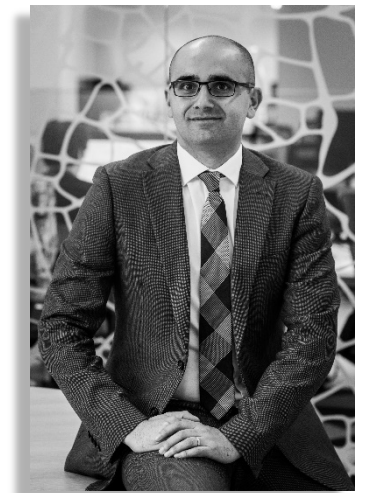


European Standardization Organizations

Thank you!

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- Websites: www.cencenelec.eu, www.cen.eu and www.cenelec.eu
- Area with [training documentation](#)
- CEN-CENELEC Newsletter: [‘On the spot’](#)
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- [CEN Members](#) and [CENELEC members](#)
- [10-10 webinars](#) & [webinars for standard drafters](#)

Important contacts CCMC

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Support on research projects



European Standardization Organizations

Thank you!

Next webinars

2021-07-06 – second webinar [‘Harmonized European standards: Drafting standards compliant with EU legislation’](#)