



European Standardization Organizations

Drafting Harmonized Standards in support of the Artificial Intelligence Act (AIA)

Purpose of this presentation

- What is a Harmonized Standard (hEN) with elements of context
- Anticipate good practice for the development of hEN specifically for AI
- Set the frame for the development of hEN

Abbreviations

EN – European Standard

hEN – harmonized European standard

ENQ – enquiry (equivalent to DIS or CDV)

FV – formal vote (equivalent to FDIS)

SR – standardization request

SRAHG – standardization request ad hoc group

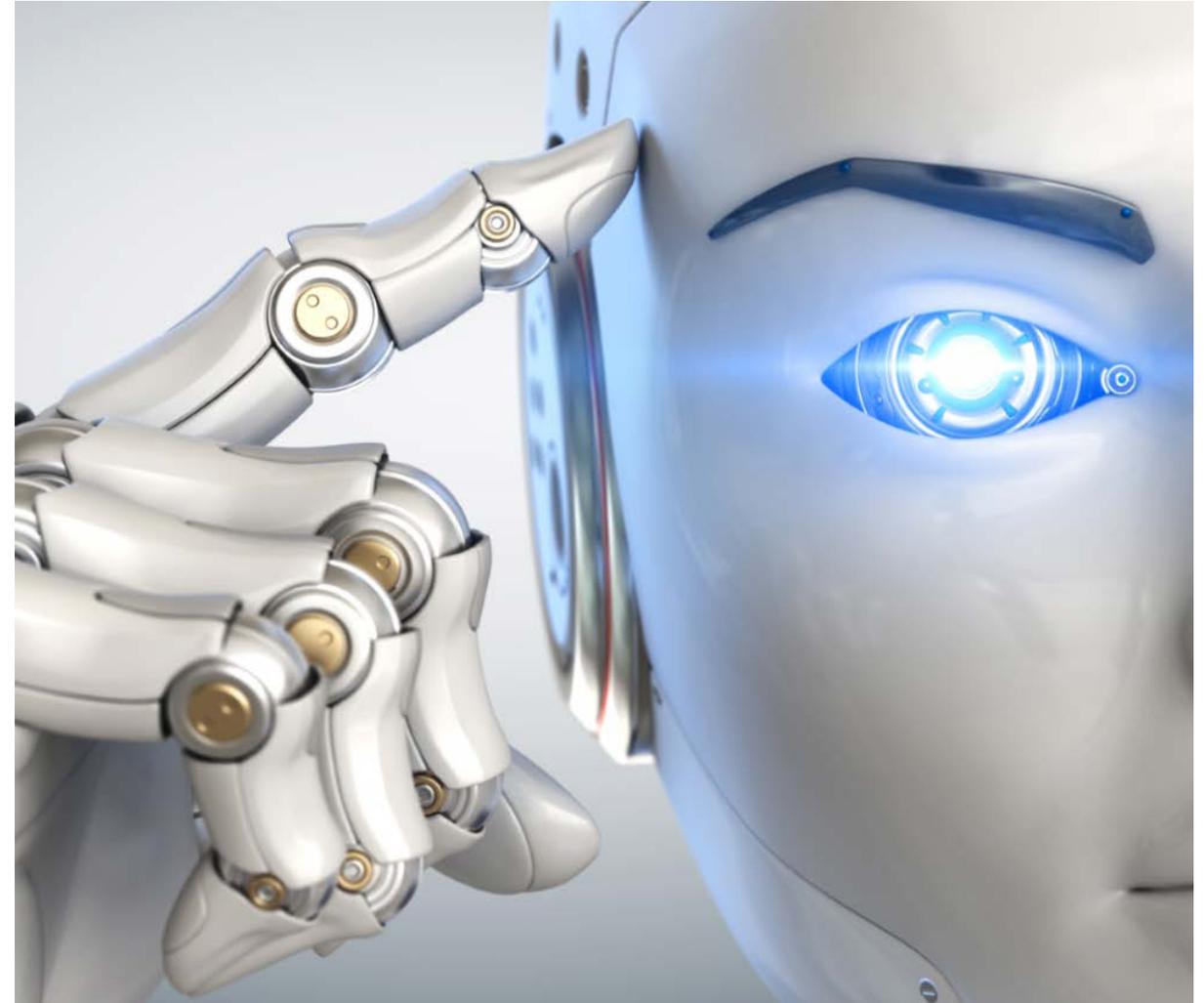
HAS consultant – harmonized standards consultant

NLF – new legislative framework

PoC – presumption of conformity

EC – European Commission

OJEU – official journal of the European Union



▶ Standards are not Legislation!

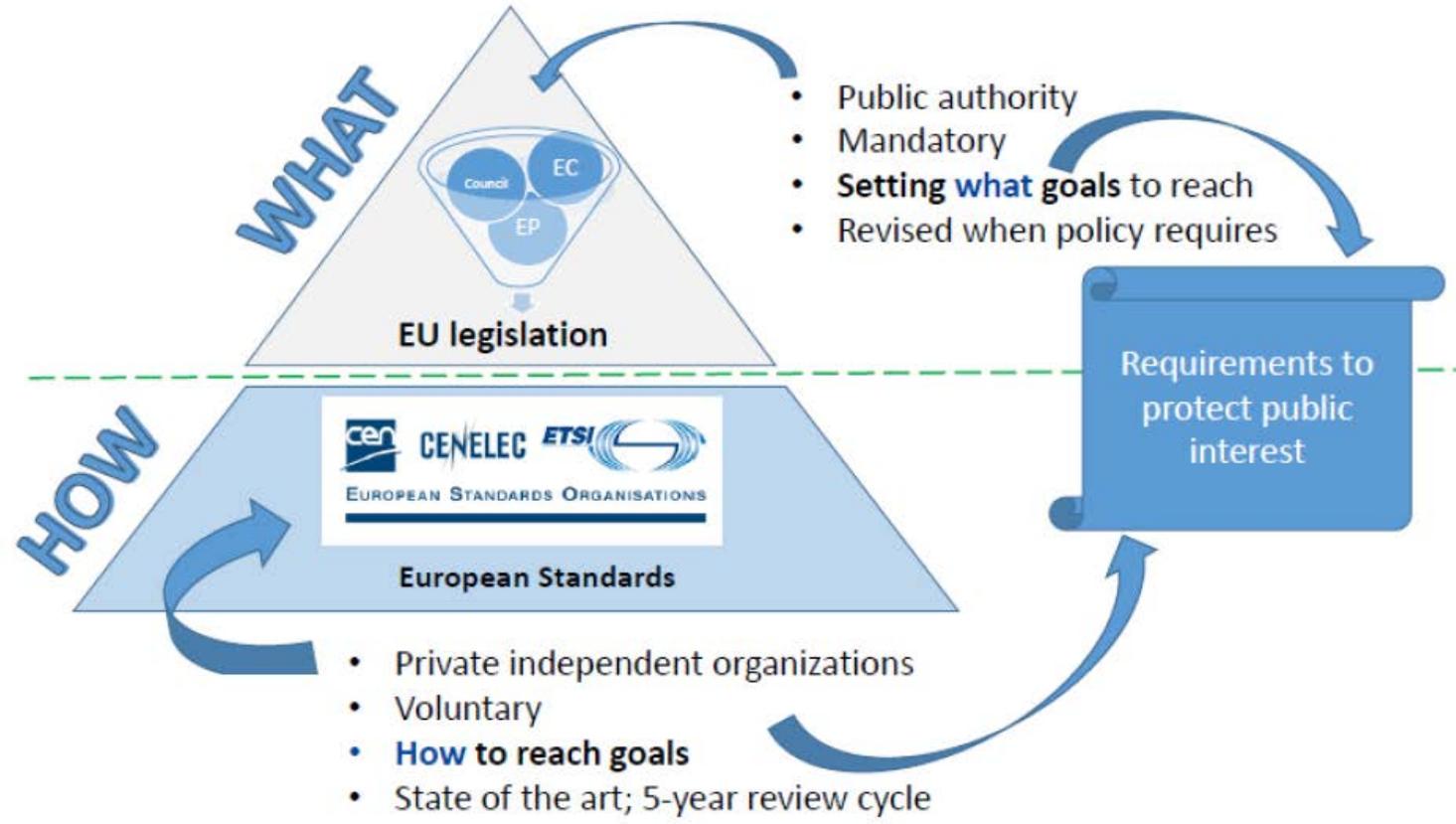
▶ Standards :

1. Voluntary
2. Consensual
3. Developed by independent organisations
4. Reviewed every 5 years
5. Provide specifications and test methods (interoperability, safety, quality, etc.)

▶ Legislation :

1. Mandatory
2. Imposed by Law
3. Established by public authorities
4. Revised when legislators decide
5. Gives requirements to protect public interests

ENs in support of EU legislation



► New Approach legislations

- foresee that the ESOs, following a standardization request given by the European Commission will elaborate hENs which will offer technical solutions to meet the Essential Requirements

► Another principle is related to **Conformity Assessment policy**:

- **Standards remain voluntary** – no obligation to implement standards
- However, manufacturers and economic operators will have to carry the burden of demonstrating that their own technical specifications meet the essential requirements – a process that involves a third party conformity assessment body
- Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements – manufacturers and economic operators may benefit from simplified conformity assessment procedures



EU harmonisation legislation

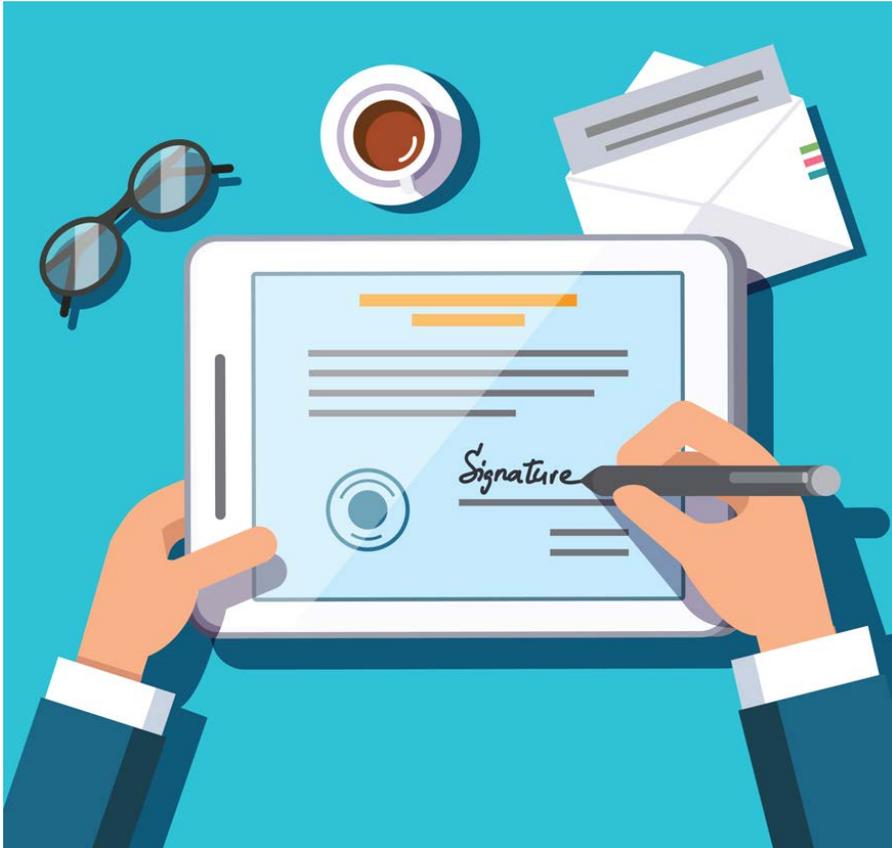
- ▶ New legislative framework (2008)
 - Objective: enhance level of trust between Member States and increase consistency (harmonisation) across all New Approach legislations
 - There was a clear need to improve: the overall coherence and consistency, the notification process, the accreditation and the conformity assessment procedures, the CE marking and market surveillance
 - Main purpose: same definitions, same conformity assessment procedures, same accreditation and market surveillance system



The NLF consists of:

- EC Regulation N° 765/2008 on accreditation and market surveillance
- Decision N° 768/2008/EC on establishing a common framework for the marketing of products
- EC Regulation N° 764/2008 to strengthen the internal market for a wide range of other products not subject to EU harmonization

- ▶ Benefits of using Harmonized Standards under the NLF:
 - Elaborated in open and transparent manner
 - fit for purpose (technical relevance)
 - Adopted by CEN and CENELEC (and ETSI)
 - fit for the EU market (market relevance)
 - (When) cited in the OJEU → provide presumption of conformity with EU legislation
 - fit for Member States (EU policy relevance)



- ▶ **Presumption of conformity is**
 - provided when the product complies with the hEN that is cited in the OJEU
 - open for anyone (voluntary)
 - granted (to the manufacturer or economic operator),
 - opposable (to Member States) – provided that the hEN is cited in the OJEU, used in the design of the product, cited in the Declaration of Conformity

► The European Commission has recently launched an [evaluation of the New Legislative Framework](#)

- The evaluation will consider **how far the New Legislative Framework has been able to accommodate recent market trends and developments overall, such as frequent changes to products after they have been placed on the market** (e.g. due to software updates and upgrades; AI and machine learning; refurbishment and remanufacturing)
- Due to their nature and specifications, more and more products can see their **hardware and software modified after they have been placed on the market and during their whole lifecycle**. Software and firmware improve the functionality, reliability, and security of everyday products on a regular basis.
- AI technologies will also have a greater impact on a products' functionalities. Moreover, **products may integrate different, evolving services and processes in complex designs**. All those elements are becoming common, as most products contain ICT components.
- Addressing product conformity for products that evolve after being put on the market may represent a challenge for the future of the NLF. **The NLF should address the way products may be evolving during their lifetime, to support their free trade and ensure their continued safety and security**

What is a harmonized standard?



Harmonised Standards

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

The references of harmonised standards must be published in the Official Journal of the European Union. The purpose of this website is to **provide access to the latest lists of references of harmonised standards** and other European standards published in the Official Journal of the European Union (OJEU).

References of harmonised standards and of other European standards published in the OJEU

What is a harmonized standard?



What is a harmonized standard?

- ▶ A harmonized standard (hEN) is a European Standard (EN) developed in response to a formal Standardization Request (SR) of the EC

Two (main) types of hEN

- **Not for citation** in the OJEU
- Requested by the EC for example to address certain standardization gaps
- Can be a basis for the development of hEN that will be intended for citation in the OJEU

- **hEN intended for citation** in the OJEU
- Provide presumption of conformity (PoC) with EU legislation

What is an AI harmonized standard?

- ▶ Considerations for the development of the 1st phase hEN
 - Standards, deliverables and projects from SC 42 should be considered according to their adequacy, technical relevance to the EU context/AI regulation
 - Original work from JTC 21 is necessary only if a gap is technically described or if the SC 42 standards could not be made available by the standardization request's deadline
 - Since, within this 1st phase, the requested standards will not be intended for being cited in the OJEU, the European Commission can request the development of standards that will not only relate to a future presumption of conformity (i.e. original work from JTC 1, adoption of SC 42 standards or parallel development of standards with SC 42 – according to the deadline and the requirements)



The objective of the 1st phase is to develop a coherent and fit for purpose set of European Standards

What is an AI harmonized standard?

► The SR can for instance request standards:

- In support of the (draft) essential requirements
→ these could be cited in the frame of the 2nd phase
- To harmonize terminology and concepts
→ these could not be cited in the frame of the 2nd phase
- For management system
→ adoption of ISO/IEC 42001?
→ don't relate to product as such, so might not be cited but can be requested by the EC to have a coherent portfolio of harmonized standards
- For risk management
→ adoption of ISO/IEC 23894?
→ don't relate to product as such, so might not be cited but can be requested by the EC to have a coherent portfolio of harmonized standards
- Cooperation with other technical committees
→ for the development, adoption or parallel work of relevant standards (e.g. ISO/IEC 27000 series already adopted as EN by CEN-CLC/JTC 13)



What is an AI harmonized standard?

- ▶ Therefore, within the 1st phase, the focus will have to be put on the development of a coherent set of standards for AI
 - That will be made available according to the standardization request deadline
 - That will be made of standards coming from SC 42 (adoption or in parallel) or pure homegrown ENs (those homegrown EN can normatively reference ISO/IEC standards and possibly relevant standards from other organisations (e.g. IEEE))
 - That will address the requirements of the standardization request

- ▶ Since the 1st phase will not request the development of hEN intended to be cited in the OJEU, it is not expected to work with HAS consultants to assess the compliance of the standards – nevertheless, this 1st phase shall be the occasion to draft hEN that could be already as much compliant as possible – for their future citation in the OJEU (see last part of the webinar)

- ▶ HAS consultant(s) would be involved in the 2nd phase

Consultant(s)





- ▶ **Standardization Request Ad-hoc group (SRAHG)**
 - ▶ Established **upon reception** of the first (informal) draft
 - ▶ Announced together with the **announcement of the first web-conference and a 'call' for nominating experts** to the SRAHG:
 - ▶ BT members and Permanent Delegates
 - ▶ Experts nominated by NSBs and NCs
 - ▶ relevant Technical Body(ies)
 - ▶ relevant Sector Forum and/or Coordination Groups
 - ▶ CEN and/or CENELEC Partners and Annex III organisations
 - ▶ Possibly ISO/IEC representatives, EC representatives, ETSI
 - ▶ Disbanded after approval/rejection of SReq

- ▶ **Standardization Request Ad-hoc group (SRAHG) role**
 - ▶ Ensures **prompt coordination** between and input from all relevant stakeholders including - CEN BT Members and CENELEC Permanent Delegates, Partner Organizations as well as other relevant parties, during the drafting and approval of Standardization Requests
 - ▶ **Provides advice** to CEN and CENELEC Technical Boards on the acceptance/rejection of the Standardization Request

Purpose of a SRAHG

► Preparation – consultations on the draft:

- with NSBs and NCs representatives and relevant stakeholders (in particular “Annex III organisations” and interested CEN and/or CENELEC partners)
- EC Vademecum on ‘European Standardisation’ – Part II ‘Preparation and adoption of the Commission’s standardisation requests to the European standardisation organisations’:
*“The sectoral departments **should endeavour to prepare requests that the ESOs will find acceptable**. The technical content of drafts submitted and the deadlines in them should therefore have already been agreed with the ESOs” and “The **Commission should submit a request to draft European Standards and European standardisation deliverables for formal adoption only when it is confident that it will be acceptable to the ESOs.**”*

→ Hence, establishment of a Standardization Request Ad Hoc Group (SRAHG) to focus on the development of a SR that will be acceptable

Purpose of a SRAHG



- ▶ **SRAHG tasks (1) → The SRAHG will**
 - ▶ Steer the preparatory work associated with the Standardization Requests and in particular issues relating to
 - ▶ Reasonable deadlines;
 - ▶ Key aspects that may affect the technical work to be clearly highlighted;
 - ▶ Timeframe (considering the possible need for financial support);
 - ▶ Resources/expertise (Technical Bodies having to carry out the work);
 - ▶ Need for financial support;
 - ▶ Dependency and collaboration between the ESOs, ISO and IEC and their involved Technical Bodies.

Purpose of a SRAHG



▶ SRAHG tasks (2) → The SRAHG will

- ▶ Collect, consider and compile comments received during the Technical Boards consultations
- ▶ Consolidate the CEN and CENELEC inputs to the EC during the various stages of the drafting of Standardization Requests;
- ▶ Agree on the proposal for acceptance or rejection of Standardization Requests to the Technical Boards;
- ▶ Once the (final) draft SReq, as submitted by the EC to the Committee on Standards (CoS), is available, BT takes a decision taking into account the SRAHG position.

TCs responsibilities

Participation in SRAHG is crucial!

▶ In SRAHG

- ▶ Actively contribute to SRAHG (provide content, etc.)
- ▶ Highlight key aspects that may affect the technical work
- ▶ Verify proposed deadline according to workload and available expertise in the Technical Committee
- ▶ Keep in mind → Positive opinion on SReq = commitment from the TC to **timely** deliver the agreed deliverables (in line with SReq)

TCs responsibilities

SRAHG disbanded after SReq approval/rejection by CEN and/or CLC!

- ▶ **When SReq allocated to a TC**
 - ▶ Prepare Work Programme (usually requested in a short time after the notification of the SReq)
 - ▶ Prepare Annual Report in time (usually 1st Annual Report requested after 1 year of the notification of the SReq)

How are harmonized standards made?

CCMC receives
draft SR
& launches call
for SRAHG
participation

EC provide
final SR to
CEN & CENELEC

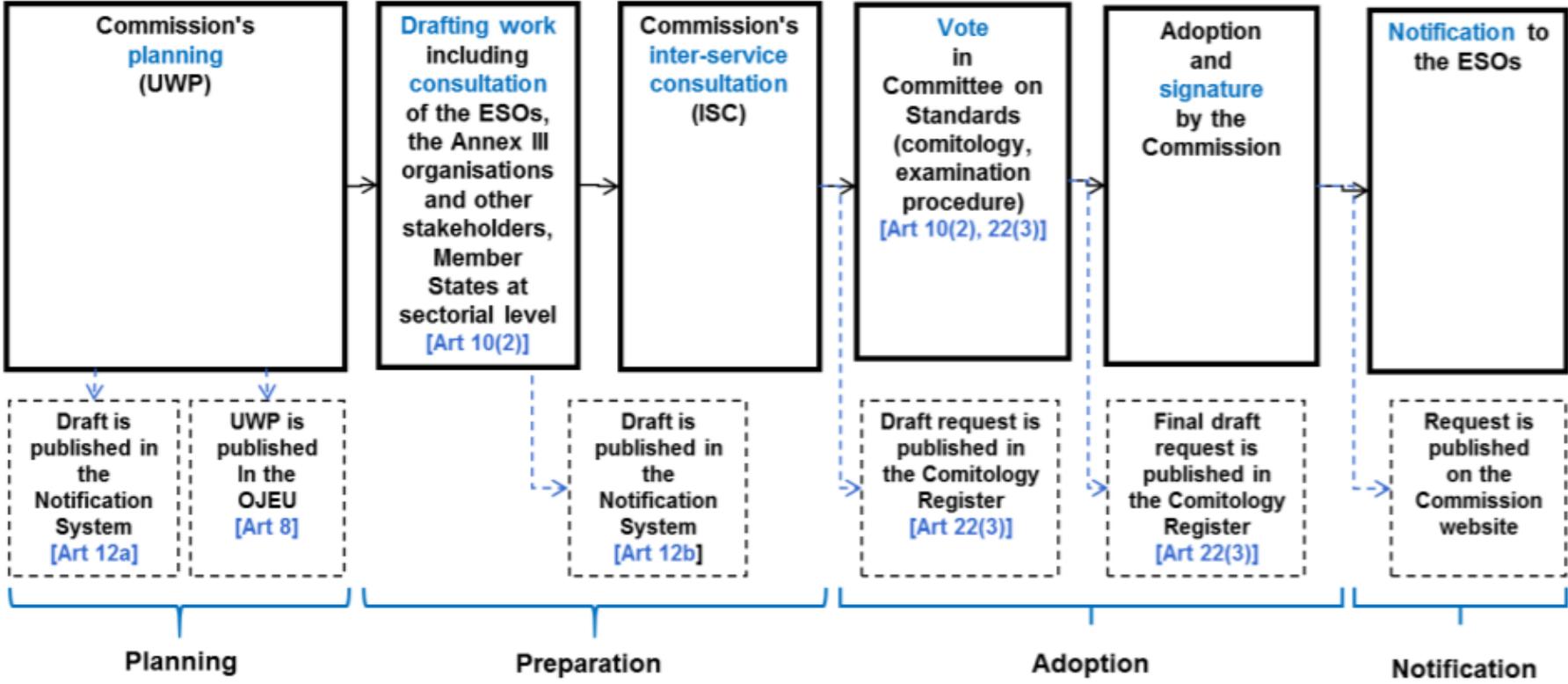
CEN & CENELEC
develop the
requested
standards

SRAHG and EC
iteratively
improve **draft** SR
until it is
acceptable for all
parties

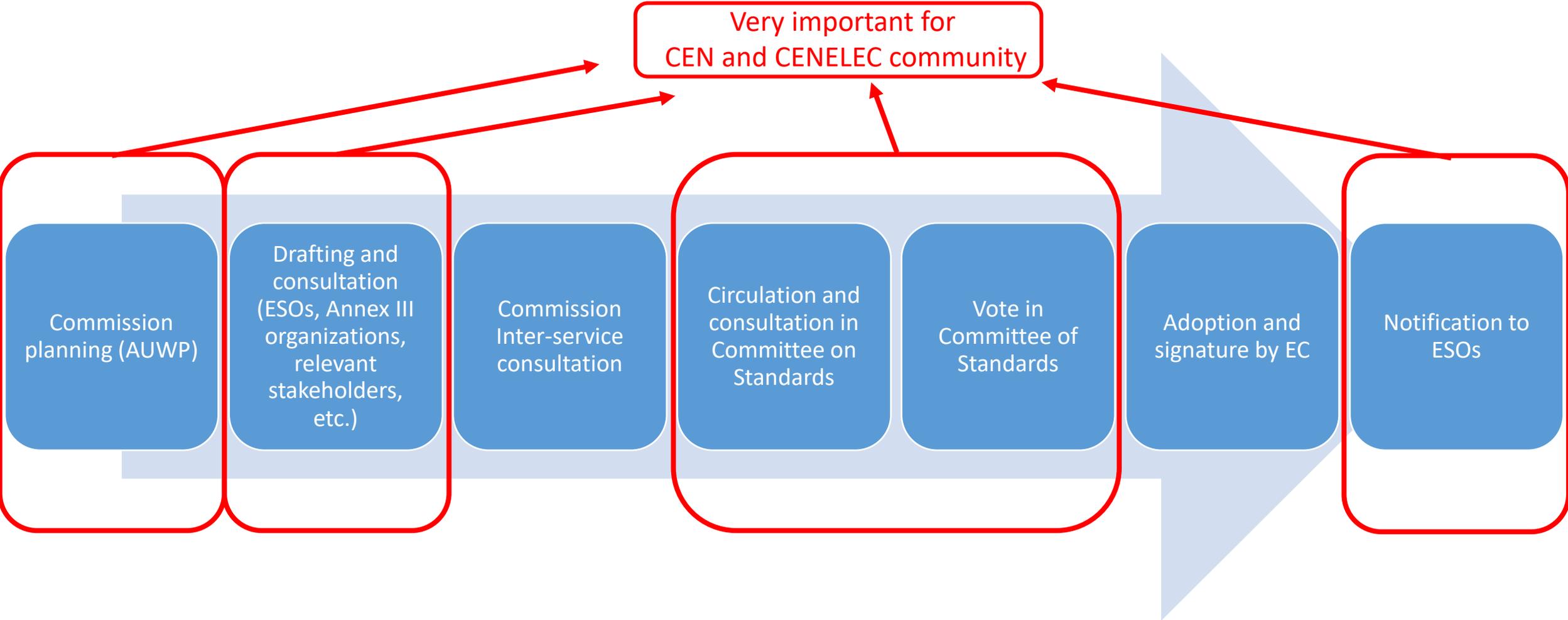
CEN & CENELEC
Technical Boards
accept or reject
the SR based on
advice of SRAHG

Standards made
available - and then
cited in the OJEU (in
case the SR calls for
the development of
hEN intended for
citation in the OJEU)

Workflow – European Commission



Workflow – CEN and CENELEC



hEN intended for citation: requirements

- ▶ Beyond the compliance to the requirements in the standardization request, hEN intended for citation shall comply with the “horizontal” requirements that allow the citation of hEN in the OJEU
- ▶ Whether we like it or not, the James Elliott judgement of the EUCJ considers that **harmonized standards are a measure of EU law after citation in the OJEU**. Since their development is entrusted to private organisations (ESOs), it follows that this assignment must be a “controlled delegation” in which the European Commission plays a fundamental role



hEN intended for citation: requirements

- ▶ HAS consultants should be available (in the 2nd phase) to perform the task of assessing whether the hEN are “compliant”. In doing so, the HAS consultant assesses whether the requirement in the regulation and in the standardization request have been properly addressed.
- ▶ The HAS consultant also assesses the hEN respect the horizontal (and possibly vertical) checklist(s) for HEN, as well as the compliance with the CEN and CENELEC Internal Regulations Part 3 (which are based on the ISO/IEC directives part 2)
- ▶ The HAS assessments on the compliance of the HEN help the EC in assessing the suitability for the citation of the HEN in the OJEU – however, the assessment results are not binding for the EC

What is at stake:

- ▶ even if the 1st phase HEN are not intended for citation
- ▶ JTC 21 and any other relevant TC needs to draft them in the spirit of a future citation
- ▶ clear any compliance issue from the start!

Requirements for citation - overview

1. Clear Scope
2. Normative references – must be dated
3. objectively verifiable requirements and test methods
4. Risk assessment and risk reduction
5. Neutrality principle
6. Annex ZA (CEN) or Annex ZZ (CENELEC)
7. Compliance with horizontal and sectorial checklists

1. Requirements for citation – scope

- ▶ 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 Regulations Part 3 (and ISO/IEC Directive Part 2), the scope shall not include requirements, permissions or recommendations. The scope shall be consistent regarding content covered by the standard.
- ▶ The scope of the standard could be broader than the relationship between the standard and the requirements of the EU legislation.

1. Requirements for citation – scope



Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant	Examples from assessments Extract from the standard
<p>The Scope excludes products or aspects that are expected to be covered by the standard according to its title or Annex Z in order to support relevant EU legislation or standardisation Request. This means that there is not consistence between the title, the scope and Annex Z; as a result, products that are expected to be covered are excluded.</p>	<p>The scope provides statements that shall not be provided in the scope of the document, or -if so- shall be rephrased.</p>	<p>In locations where special conditions prevail, such as in ships, vehicles and the like and in hazardous locations, for example where explosions are liable to occur, special construction and/or additional requirements may be required</p>
	<p>A standard ensuring safety of a component shall be characterised by addressing safety aspects of the component and have the component type in its scope.</p>	
	<p>The scope contains normative requirements to other standards. For the intended use of the scope see IR3. The scope is to limit the applicability working range of a standard, not to declare requirements for equipment out of the scope If the exclusions need to remain normative, just state that these categories of equipment are not within the scope. If the TC wants to keep the standards references, make these informative. For the intended use of the scope see IR3 14.1: The scope clearly defines the subject of the document and the aspects covered, thereby indicating the limits of applicability of the document or particular parts of it.</p>	<p>“For devices used next to the body or in front of the face the applicable product standard is EN 50566:2017. For low power devices the applicable product standard is EN 50663:2017.”</p>

2. Requirements for citation – normative references



- ▶ The CEN-CENELEC Internal Regulations – Part 3 include provisions on the use of normative references.
- ▶ The normative references shall be **dated, active and published**
- ▶ Non-dated normative references are exceptionally possible if:
 - The normative reference is not relevant for compliance with essential requirements or
 - The normative reference is relevant for compliance with essential requirements but the implications of modifications to the referenced document for the compliance with essential requirements have been duly considered (to be explained in a dedicated Technical Body justification, which will have to be provided to the HAS consultant).
- ▶ As a general principle, all normative references must be **EN, ISO or IEC standards**. If EN, ISO and IEC standards do not exist, exceptionally, other standards could be used under certain conditions:
 - The references must comply with the ISO/IEC Directives Part 2
 - The document needs to be available for possible consultation by the HAS consultant or the European Commission.
- ▶ CEN and CENELEC have developed a proper guidance document on these aspects. Moreover, it is expected that the standardization request will address the aspects of possibly referencing IEEE standards

2. Requirements for citation – normative references



Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
<p>The normative references need updating or reconsideration, i.e.</p> <ul style="list-style-type: none"> • one or more do not reflect the state of the art and have an impact on compliance with EU legislation, • one or more normative references, in particular references to other harmonised standards should be informative (to avoid later contradictions because of different update cycles of referring and referenced documents) 	<p>The normative reference chain contains links to legislations, undated references. Potentially different versions of the same document, and a circular reference</p> <hr/> <p>In the list of normative references are the Council Recommendation 1999/519/EC and the directive 2013/35/EU. This is normally not allowed to refer to legislation in a standard.</p>

3. Requirements for citation – requirements & test methods

- ▶ The hEN shall contain **objectively verifiable requirements and test methods** – in line with the CEN-CENELEC Internal Regulations Part 3 and the ISO/IEC Directives Part 2: “Expression in the content of a document conveying objectively verifiable criteria to be fulfilled and from which no deviation is permitted”.
- ▶ Only those requirements which can be verified shall be included. Phrases such as “sufficiently strong” or “of adequate strength” shall not be used because they are subjective statements.
- ▶ Furthermore, **technical requirements that are not linked to the EU legislation’s essential requirements shall be covered in separate clauses in the standard**. Similarly, separate EU-related requirements (e.g. Machinery?) shall be covered in separate clauses. This particular point of attention may require some evolutions in the structure of the SC 42 standards.



3. Requirements for citation – requirements & test methods



Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
The technical content of the document unsuitably repeats legal requirements as part of its normative requirements (e.g. without any added value or modifying them, suggesting that only some legal requirements are valid)	the text duplicates a directive’s legal requirement, leading to confusion and legal problems

Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
Absence of reproducible tests or assessment methods (or lack of reference to standards containing such tests or assessment methods) to demonstrate in a objectively verifiable manner the technical specifications in support of the Essential Requirements and indicated in Annex ZA/ZZ, or the foreseen assessment methods are not suitable	Although routine tests have been defined for some devices/components in this standard, a routine test for the final equipment within the scope of this standard, is not defined (this is a requirement of the LVD, see annex 1, 1c).
	Alternate test methods presented without technical justification nor objectively verifiable proof of equivalence. Can the TC explain why an alternate test method is provided without guidance to the reader on when and how each method is to be preferred, required or necessary.necessary? If the test methods are equivalent, then no proof of equivalence is to be provided. In general, if a test method is different, it’s contextual restrictions are different and shall be made clear.
	Requirements for measuring instruments are provided in this standard, however requirements for test instruments are missing. Tolerances for accuracy of measurement/testing are here and there in the standard (e.g. in G.5.2.2 and G.5.3.4.5), however measurement uncertainty requirements are missing (see also B.2.5 lines 6642-6643).
	This statement “according to the test specifications of IEC 60730 series” is a very broad. There is however a specific standard for thermal cut-offs, i.e., 60730-2-9:2015 + AMD1:2018.
	the standard contains more than one test alternative (page 40) without guidance or priority indications but for the level of conservatism and computational effort.
	Choice on alternate test methods non-justified
	The additional risks due to the inclusion of radio equipment (function or appliance) do not appear to be addressed. Can the TC explain how ay risks associated with intentional or non-intentional (criminal?)and intended “remote control” of the equipment shall be covered? Safeguards shall be implemented during use by ordinary users, but also during service by skilled workers.

4. Requirements for citation – risk reduction



- ▶ If a hEN deals with safety or security aspects, the relevant hazards must be identified, and the risks reduced.
- ▶ There is no particular template for such a risk assessment, however it should rely on
 - [CENELEC Guide 32](#) ‘Guidelines for safety related risk assessment and risk reduction for low voltage equipment’.
 - See also an [example on how CLC/TC 23E uses CENELEC Guide 32](#) for its risk analysis and self-assessment.

Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
Risk assessment or identification of relevant risks is missing or not complete and/or there is no evidence that certain risks were considered	I have found no risk analysis addressing possible other risks associated with radio, such as remote control and/or firmware
	There are no requirements for radio, nor requirements for radio related risks, such as remote control, nor a reference to a risk analysis covering these risks.
	It can be acceptable that a standard cover only 3.1(a) and 3.1(b) but such shall be reflected in the scope.
	With respect to mechanical, electrical and thermal safety requirements, these are considered fully covered, if the lighting equipment with the built-in radio equipment complies with the relevant clauses of the corresponding standard.
	Make this part of the clause numbered 4.2 Can the TC explain how other risks are being covered (beyond the 3 mentioned) ?
	Electrical, mechanical and thermal safety Other risks shall be addressed too, such as fire, dust and moisture as well as (non-EMF) radiation.
	Requirements for measuring instruments are provided in this standard, however requirements for test instruments are missing. Tolerances for accuracy of measurement/testing are here and there in the standard (e.g. in G.5.2.2 and G.5.3.4.5), however measurement uncertainty requirements are missing (see also B.2.5 lines 6642-6643).
	MU defined in a referenced standard is referred to as “reasonable”, and not as a standards firm requirement By reference to Table 3 in EN 62369-1 is not definite in defining MU (“reasonable”) . Therefore the MU in this standard by reference to 62369-1 is not expressed in terms suitable for defining presumption compliance or non-compliance.

5. Requirements for citation – neutrality principle

- ▶ For compliance purposes, the hEN must respect the neutrality principle – in line with the ISO/IEC Directives Part 2, clause 33.1.

- ▶ 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 conformity assessment.



5. Requirements for citation – neutrality principle



Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
<p>Neutrality principle is not respected: the document contains 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)</p>	<p>Several occurrences of “intended use as specified by the manufacturer” or similar phrases. Use “intended use” and “reasonable foreseeable use” instead of “intended use as specified by the manufacturer”.</p>

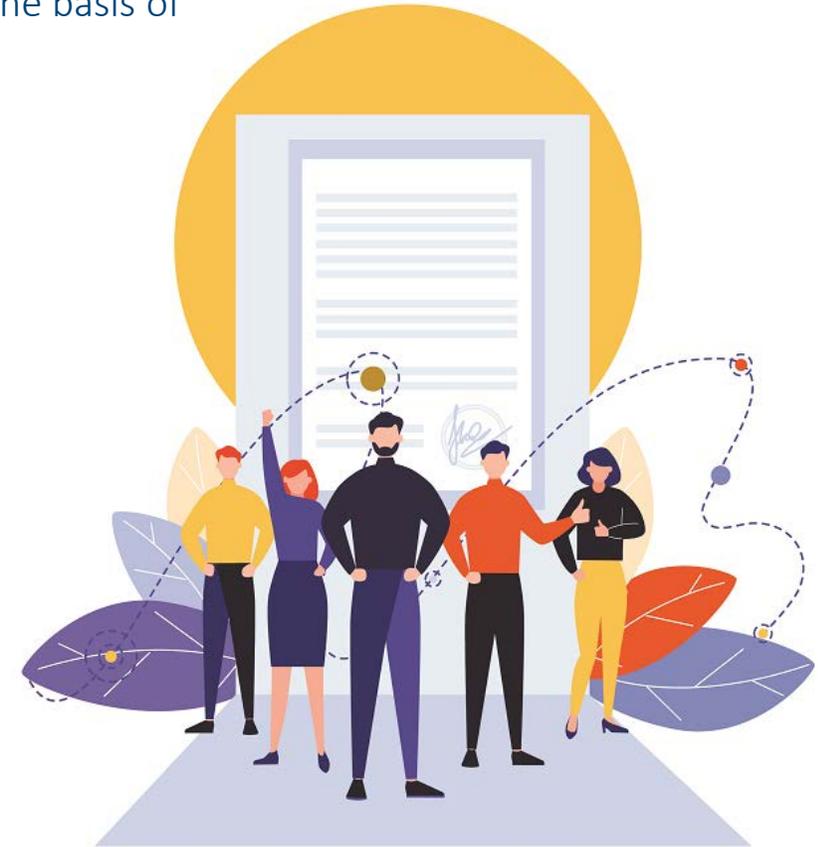
6. Requirements for citation – Annex Z

- ▶ Annex Z details which essential requirements or parts of the legislation are covered
- ▶ For the drafting of the informative Annex ZZ, the latest template shall be used
- ▶ The rows shall be placed in the order of the legal requirements.
- ▶ If a legal requirement is claimed as covered in the Annex ZZ, this requirement shall be clearly addressed by a clause/sub-clause of the standard.
- ▶ If a standard deals with aspects which are outside the scope of the EU legislation, clauses/sub-clauses dealing with these aspects shall not be referred to in the informative Annex ZZ.
- ▶ For further information on the drafting of Annex ZZ, see the [Webinar on Annexes ZA/ZZ to CEN/CENELEC Harmonized Standards](#).

Findings as in Assessment Report	Examples from assessments Comments made by HAS Consultant
The Annex Z is not sufficiently detailed (need for more granularity) in describing which clauses and sub-clauses support relevant EU legislation	The entries on emissions and immunity can be more granular, for example on the level of essential tests

7. Requirements for citation – Checklists

- ▶ EC general checklist
 - Verification of procedural formalities
 - Quantitative verification as regards the legal requirements aimed to be covered on the basis of the standardisation request
 - Qualitative assessment as regards the legal requirements aimed to be covered
- ▶ CEN and CENELEC checklist
 - European foreword
 - Scope
 - Normative references
 - EU Legal text in the standard
 - Risk reduction
 - Neutrality principle
 - Annex Z (ZA in CEN, ZZ in CENELEC)



7. Requirements for citation – EC Checklist (1/2)



Step I: Verification of procedural formalities				
1 Coverage by a relevant standardisation request and Union harmonisation legislation (Art. 2(1)(c), Art. 10(1))				
1.1	Is the standard covered by the requested-work programme of a relevant standardisation request made by the Commission?	M/511 EN	X	
1.2	Does the subject matter deal (at least partly) with a product, service or other aspect regulated by relevant Union harmonisation legislation <u>and/or</u> can the standard, on the basis of its actual content, be used to support application of legal requirements under Union harmonisation legislation (e.g. terminology and definitions alone cannot confer any presumption of conformity)? (see also corresponding act)	Supports the Safety Objectives of 2014/35/EU	X	
1.3	Is the title of the standard translated into all official languages?	---	---	---
1.4	In cases of a family of standards or multiple parts only: Is there a meaningful set of different parts which could be cited in the <i>OJ</i> at the same time <u>or</u> is there absence of other reasons for citing only a single part?	N/A		
1.5	In cases of revised versions of harmonised standards already cited in the <i>OJ</i> only: Are significant changes clearly indicated in the revised or amended standard? (see SWD(2015) 205 Part 2, section 3.5; model Article 5 and the relevant request; SWD(2015) 205 Part 3, section 2.10.4)	See Foreword	X	
2 Transparency and inclusiveness during requested standardisation work (Art. 3(1)-(4), Art. 5, Art. 6)				
2.1	Was the work item for the standard included appropriately in the requested-work programme? (see SWD(2015) 205 Part 3, sections 2.3 to 2.5)		X	
2.2	Absence of any concerns as regards inclusiveness during drafting and adoption?		X	
3 Absence of a formal objection or any information on a possible objection (including other objected harmonised standards to which there are normative references, where relevant)? (Art. 11)			X	
4 Legal requirements aimed to be covered are indicated (Annex Z or equivalent informative element is available) and, where relevant, expressed separately for each relevant Union harmonisation act to be supported? (Art. 10(6); SWD(2015) 205 Part 2, section 3.6; Part 3, section 2.8.4)			X	
5 Normative references made in clauses or sub-clauses which support legal requirements (SWD(2015) 205 Part 3, section 2.8.3)				
5.1	Are all standards to which there are normative references publicly available, i.e. normative references have been adopted and/or standards are still valid, and are there no references to draft standards (relevant during the final assessment of an adopted standard only)?		X	
5.2	Is it possible to have access in all official EU languages to <u>the most relevant</u> standards to which there are normative references? [1]		?	
5.3	Is there an absence of undated normative references?		X	
5.4	Complete <u>normative reference chains</u> (i.e. further normative references contained in a normative reference) need to be followed and each level verified according to 5.1 to 5.3. Is there absence of any concerns on these other levels of normative references?		X	

7. Requirements for citation – EC Checklist (2/2)



Step II: Quantitative verification as regards the legal requirements aimed to be covered <u>on the basis of</u> the standardisation request (Art. 10(1), 10(6))			
6 Clarity and transparency of normative parts of the standard which aim to support the legal requirements aimed to be covered (SWD(2015) 205 Part 3, section 2.8.4)			
6.1	<p>Are the legal requirements (e.g. ‘essential’ requirements) aimed to be covered indicated clearly, transparently and in a structured way, so that Step III qualitative assessment can be carried out for each (in the case of Annex Z or equivalent informative element, this includes legally sound statements, references only to normative elements of the relevant standard, no reference to other standards) <u>and</u> do the normative elements of the standard contain no references to legal acts [2]?</p> <p>[Where covered legal requirements and/or relevant clauses and sub-clauses cannot be identified, consider giving a ‘no’ answer and move on to question 6.2] [‘Yes’ answer: consider each ‘requirement aimed to be covered’ in Step III and skip question 6.2]</p>		X
6.2	<p>Does the standard itself otherwise make clear to the reader which legal requirements it is intended to cover, through clearly identifiable clauses and sub-clauses (to allow for continued verification in justified cases, even where a specific Annex Z or equivalent informative element is missing)?</p> <p>[If ‘yes’, consider each ‘requirement aimed to be covered’ in Step III <u>and</u>, where references are published in the <i>OJ</i>, publish a notice listing these requirements; if ‘no’, stop the process here — the standard must be amended to indicate which legal requirements are actually aimed to be covered]. [2]</p>		X
7 The standard does not contain normative elements outside the scope of supported legal requirements addressed in the relevant request(s) (whether or not clearly indicated in Annex Z or elsewhere)?			
[A ‘no’ answer means that normative elements are not restricted to supporting legal requirements only; move on to question 8 in Step III — otherwise skip question 8].			
Step III: Qualitative assessment as regards the legal requirements aimed to be covered (Art. 10(1), 10(6))			
8 Absence of specifications (in ‘non-harmonised content’) which:			
	<p>(a) are incorrectly or inappropriately linked to supported legal requirements despite having nothing to do with such requirements; or</p> <p>(b) aim to provide interpretations regarding other regulated issues outside the scope of the relevant standardisation request (absence of unaccepted interference with other EU legislation)? (SWD(2015) 205 Part 1, section 7.1; Part 3, sections 2.8.2 and 2.8.4)</p> <p>[If ‘no’, consider stopping the process here — the standard must be amended to reflect the scope of the initial request] [3]</p>		X

7. Requirements for citation – CEN-CENELEC Checklist (1/3)

	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	Is this draft standard listed in a Standardisation Request / covered by a Mandate?	<input type="checkbox"/>
	Is this reflected in Projex-online database?	<input type="checkbox"/>
	<i>NB: This information is normally already provided in the NWIP form. 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>	
	<i>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)? 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>	<input type="checkbox"/>
	<i>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?</i>	<input type="checkbox"/>
European foreword	<i>If the standard is a revision, are the significant changes with respect to the previous edition precisely defined? 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. 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>	<input type="checkbox"/>
	<i>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." NB: Annex ZA in CEN and Annex ZZ in CENELEC.</i>	<input type="checkbox"/>
Scope	<i>Is the scope concise and clear? Is it worded as a series of statements of fact?</i>	<input type="checkbox"/>
	<i>Are the title, scope and annex Z consistent regarding exclusion / content covered by the standard? NB: The scope of the standard could be broader than the relationship between this standard and the requirements of the EU legislation. NB: The scope shall not include requirements, permission or recommendation (in line with IR 3).</i>	<input type="checkbox"/>
Normative reference	<i>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"). NB: See IR 3 with the preferred verbal form to be used to express a requirement.</i>	<input type="checkbox"/>
	<i>Are the normative references dated in Clause 2 and in all clauses of the draft standard?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

7. Requirements for citation – CEN-CENELEC Checklist (2/3)



	<p>If not, is a justification for using undated normative references provided?</p> <p>Non-dated normative references are only possible if</p> <ol style="list-style-type: none"> 1. The normative reference is not relevant for compliance with essential requirements. <p>or</p> <ol style="list-style-type: none"> 2. The normative reference is relevant for compliance with essential requirements but the implications of modifications to the referenced document for the compliance with essential requirements have been duly considered (to be explained in the justification). <p><i>NB: Additionally, IR 3 requirements on normative references apply, i.e. the complete document is referenced, it will be possible to use all future changes of the referenced document for the purposes of the referring document and the reference will include all amendments to and revisions of the referenced document.</i></p> <p><i>NB: It is not enough to date the normative references in Clause 2 only; they need to be dated also within the main text. For series of standards the expression "all parts" is equal to undated normative references. The expression shall not be used unless a justification is provided.</i></p>	<input type="checkbox"/>
	<p>Are all the references used EN, ISO and IEC standards?</p> <p>If not, do suitable EN, ISO and IEC standards exist which could be used instead?</p> <p>If not,</p> <ul style="list-style-type: none"> • Do the references comply with IR 3 conditions (see IR 3:2019 Clause 10.2)? • is the needed TC decision (in CEN) available? • is a justification provided (preferably to be included in the TC decisions)? • has provision been made to ensure the documents are available for the assessment by HAS Consultant/European Commission? <p><i>NB: Guidance on the provision of supporting documents may be provided by the CCMC Project Manager</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	<p>Are all the normative references still active and published?</p>	<input type="checkbox"/>
<p>EU Legal text in the standard</p>	<p>Is the terminology (including definitions of terms in Clause 3) used in this standard in line or consistent with the relevant EU legislation?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

7. Requirements for citation – CEN-CENELEC Checklist (3/3)



	<p>If not, where a definition differs from relevant EU legislation, is the difference indicated in the European foreword and in Annex Z?</p> <p><i>NB: The technical content of the document shall not</i></p> <ul style="list-style-type: none"> • 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. 	<input type="checkbox"/>
Risk reduction	<p>If the standard is a product standard dealing with safety aspects, have the relevant hazards been identified and risks considered and adequately reduced?</p>	<input type="checkbox"/>
Neutrality principle	<p>Does the standard respect the neutrality principle?</p> <p><i>NB: 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).</i></p> <p><i>NB: The standard shall not contain clauses imposing first, second- or third-party assessment conformity.</i></p>	<input type="checkbox"/>
Annex Z (ZA in CEN, ZZ in CENELEC)	<p>Is the latest version of the template for the informative Annex Z used?</p> <p>Are the rows placed in order of the legal requirements?</p> <p><i>NB: The template is available in CEN/BOSS / CENELEC/BOSS (Reference material – Forms and templates). The column with the Directive/Regulation requirements shall be the first one (on the left side).</i></p> <p><i>NB: If the standard covers different EU Directive / Regulation / Decision, separate annexes Z shall be prepared.</i></p>	<input type="checkbox"/> <input type="checkbox"/>
	<p>If a legal requirement is claimed as covered in the Annex Z, is this requirement clearly addressed by a clause / sub-clause of the standard?</p> <p><i>NB: Do not indicate in an Annex Z any references of other standards (or Technical Reports, Technical Specifications).</i></p> <p><i>NB: The Annex Z shall identify which clauses (or sub-clauses) of the standard support which requirements of the EU legislation.</i></p>	<input type="checkbox"/>

Funding request to the EC

- ▶ Funding can be requested to the European Commission outside the normal funding procedure with the following steps:
 1. Filling in the **project description document**
 2. The proposal is **submitted to CEN/BTWG 217** 'Prioritization of contracts requesting co-funding from EC' for approval
 3. **Drafting the quotation** together with people from the agreement units
 4. CEN to **launch call for interest**, inviting candidates to apply for receiving funding
 5. Proceed with a **selection panel** (usually the TC officers and CCMC) to select the experts that will receive funding
 6. Creation of a **dedicated project team** (PT) within the TC to deal with the funded work

Funding request – additional information

- ▶ See [CEN & CENELEC Guide 16](#) “Request for EC financial support – Guidance to the secretariat/convenorship of the responsible technical body”



European Standardization Organizations

Thank you for your availability and attention!

ckohler@cencenelec.eu

lhernalsteen@cencenelec.eu