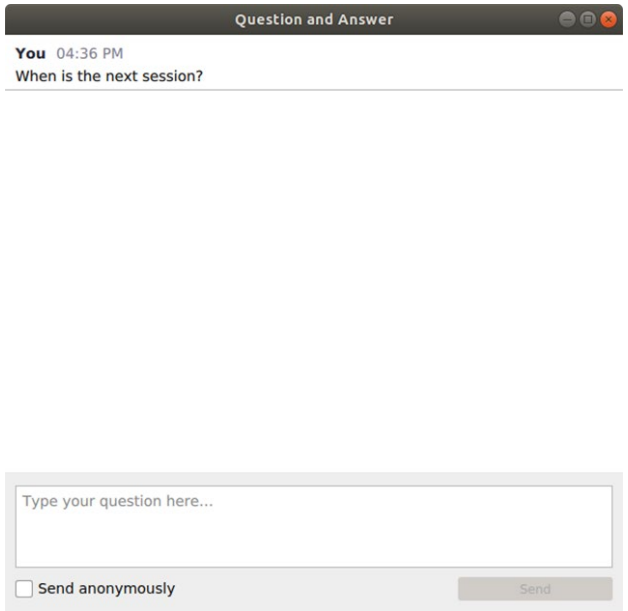
European Standardization Organizations

Drafting for compliance: best practices in Health Equipment standards

We start at 11:00

Get the most out of the webinar today

- You are muted
- Use the Q&A panel to submit your questions



- Talk about us on Twitter #training4standards @Standards4EU

Agenda

11:00	Welcome
11:05	Opening remarks by the European Commission
11:10	Key development processes and drafting reminders (CCMC)
11:25	HAS process overview & sector update (EY)
11:35	Best practices and recurring issues (HAS Consultants)
12:20	Q&A
13:00	End of the webinar

Opening remarks by the European Commission

Mario Gabrielli Cossellu (DG SANTE – Desk Officer for Medical Devices)

Key development processes and drafting reminders

Frédéric Mlanao, Account Manager at CEN and CENELEC

Innovative Process – homegrown hEN

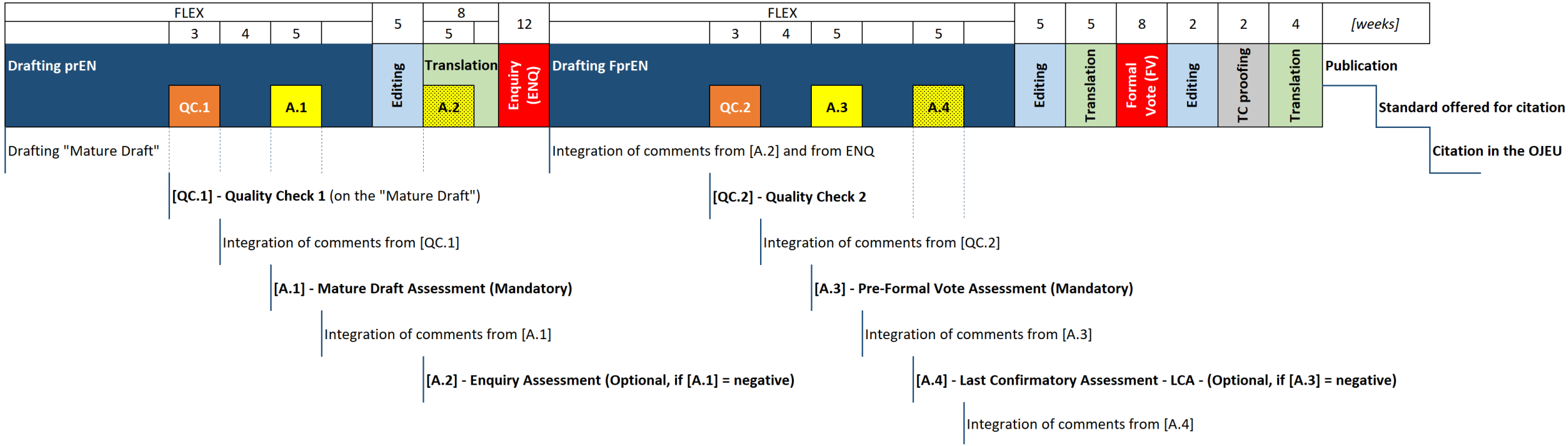
Target: To increase the number of "compliant" assessments and, in fine, the number of standards cited in the OJEU.

Innovative process based on 2 main pillars:

- Mature draft concept
  - Draft ready for ENQ
  - Mature draft assessment **mandatory**
  - Optional FWD assessment **not possible** anymore (while FWD circulation still possible)
- CCMC Quality Check
  - help Technical Bodies identify elements in the draft, or the related Annexes, that could potentially lead to a lack of compliance assessment
  - Uses Common checklist as support document

Innovative Process – homegrown hEN

Workflow

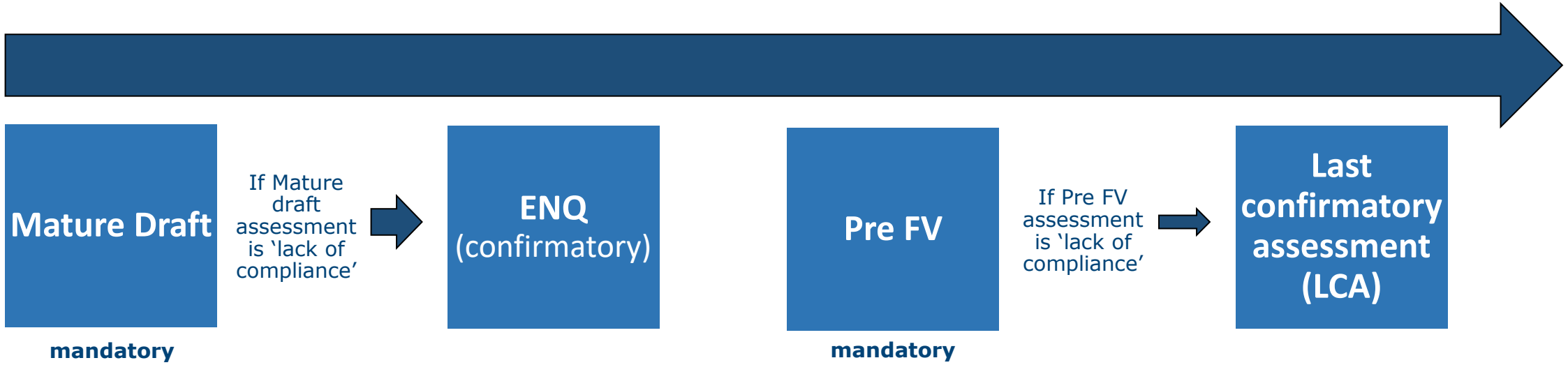


Innovative Process – homegrown hEN

Operational instruction for TC

- Step 1: WG Convenor considers the draft being a "Mature draft" and WG Secretariat sends it to TC Secretary
  - Mature Draft = Draft of an EN, before the stage of submission for the preparation of the enquiry, considered by the TC to be mature on both following dimensions:
    - Reflection of the consensus reached by the working group on the technical content;
    - Compliance to the EC requirements related to harmonized standards (criteria subject to QC and HAS assessment).
  - Attention: Mature Draft is not necessarily the first Working Draft (FWD)
- Step 2: TC Secretary fills in the "Checklist for hEN"
- Step 3: TC Secretary sends the draft and the Checklist **by email** to CCMC HSC (Harmonize Standards Compliance Team, hsc@cencenelec.eu)
- Step 4: CCMC executes the Quality Check [QC.1]
  - Duration = max. 15 working days
- Step 5: HSC sends the Quality Check results to the TC Secretary
- Step 6: TC reviews the draft based on the elements flagged during the Quality Check and submits the updated draft **by email** to CCMC HSC (Harmonize Standards Compliance Team, hsc@cencenelec.eu)
  - Duration = max. 4 weeks
- Step 6: CCMC HSC requests the Mature Draft Assessment [A.1]

When to request an assessment



- Maximum 4 assessments per WI
- LCA: full assessment, should become exceptional
- Not possible to request assessments of published standards

Parallel Projects Process

Key factors for the International Standardization process:

- **Consensus-Building** at European and International level
- **Strong Communication and Coordination** between the European TC and the International TC (specific role for secretaries, convenors and TPM)

For Harmonized ENs

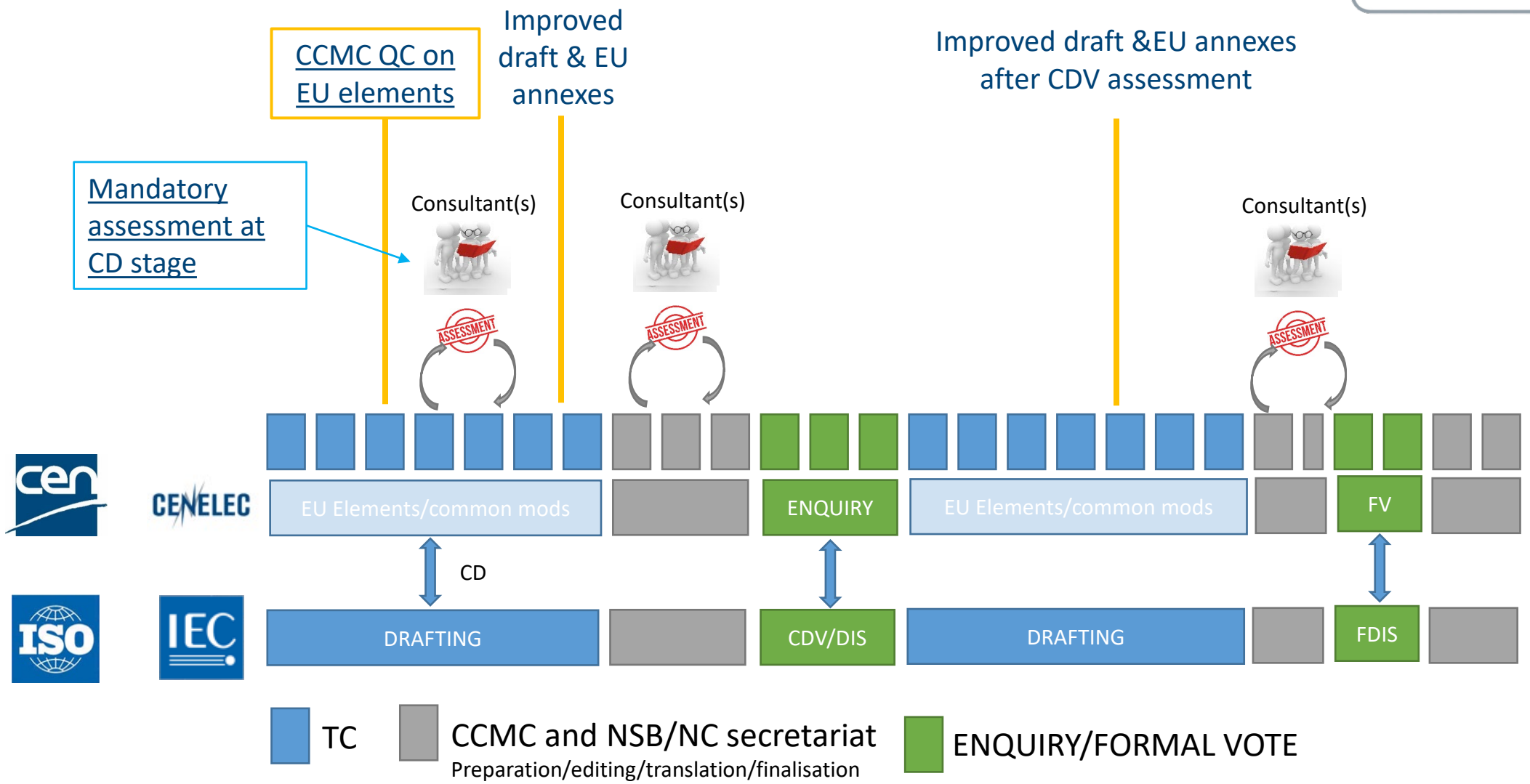
The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

‘New’ Process for Parallel Projects (hENs)

Process intended to:

- Improve timely delivery for parallel ISO/IEC Harmonized Standards
- Avoid blocked draft Standards before Publication
- Minimize interference with International Projects timeframe

‘New’ Process for Parallel Projects (hENs)



Key points for // development

- Start the process as early as possible
  - European TC invited to closely follow work at international level and to develop Annex Z in parallel with CD draft
- 'New' Process will only apply if:
  - CD available
  - European Elements available
- Communication is key
  - Ensure communication flows between CEN-CLC/TC (interaction with the HAS consultants) and ISO-IEC/TC (writing the standard)
- Common checklist not mandatory, but highly recommended when drafting European Annexes

Key drafting reminders

- Perform self assessment using Common checklist
- Draft **clear** and **verifiable provisions**

- Normative References :
  - should be **dated**, **active**, **published** when hEN is made available
  - Recommended to **refer to a specific clause** within the NR (to avoid issues with chains of NRs)

- Use CCMC guidance documents: do your homework ☺

Useful Links

- CEN webinar ‘Drafting harmonized standards - IR3 rules, requirements and normative references’
- Webpage: Drafting European standards for citation in the OJEU
- Guidance document: Guidance on normative references in harmonized standards
- Webinar 'New process for harmonized standards under parallel development’
- Webinar 'Presentation of the new EC/HAS ESOs Common checklist’
- Webinar 'Innovative process for homegrown harmonised standards (hENs)’
- Webinar 'CEN Annex ZA - Updates related to the Table ZA.2' - Experts CEN

HAS process overview & sector update

EY – HAS Support

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

Shape the future with confidence

Roles & responsibilities, processes and key tasks

Building a better working world

HAS Support Team

Joke Wiercx

Project Manager

Daan Bijwaard

Core Team Leader

Emilia Pauwels

HAS Operations Coordinator

Milko Goossens

Operational Support

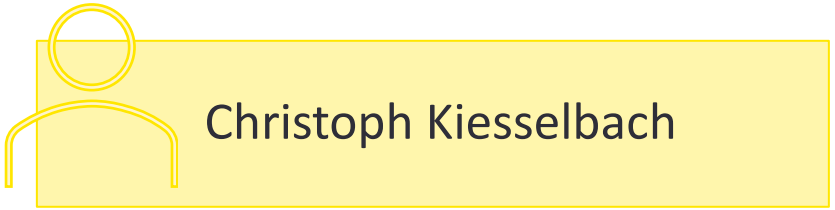
Maciej Korochoda

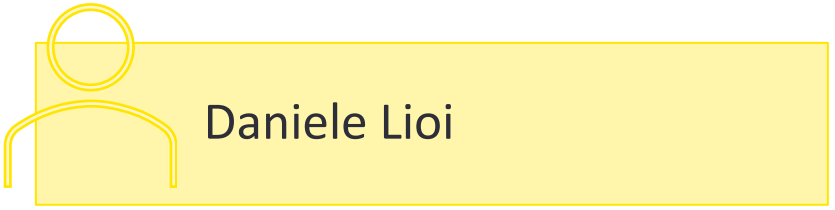
HAS Operations Executor

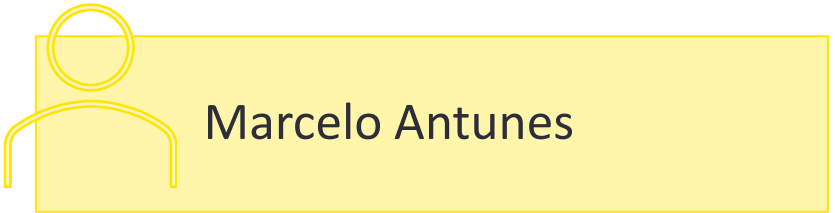
Hanna Falkiewicz

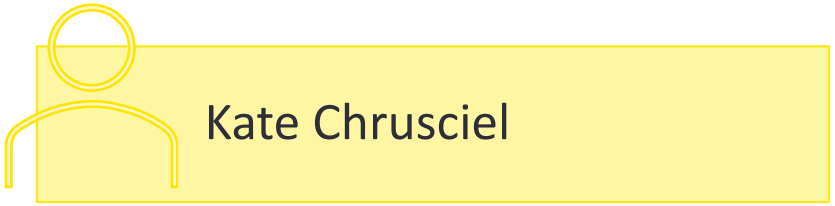
Invoicing Coordinator

HAS Consultants (HE Sector)

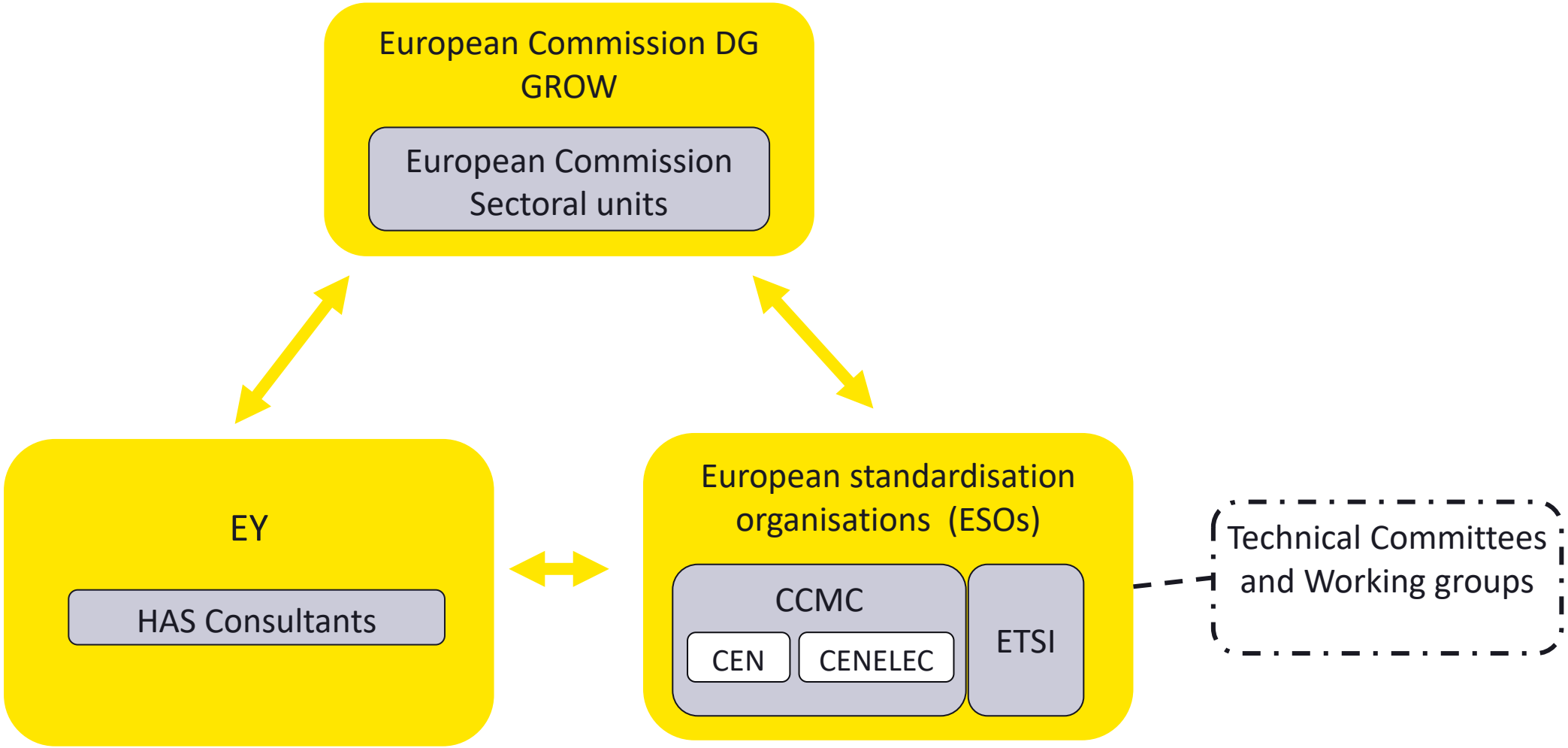








Key stakeholders



DGs involved and sectors covered

DG GROW

Unit H.2 Machinery & Equipment

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

Unit F.2 Bioeconomy, Chemicals & Cosmetics

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

Unit D.3 Market Surveillance

- New Legislative Framework (NLF)

Unit H.1 Construction

- Construction Products (CPR)

Unit I.3 Green and Circular Economy

- Eco Design (ED)

DG SANTE

Unit B.6 -Medical devices, Health Technology Assessment

- Medical Devices (HE)

DG DEFIS

Unit A.1- Defence Industry and Market Policy

- Unmanned Aircraft Systems (UAS)

DG JUST

Unit E.4- Product safety and Rapid Alert System

- General Product Safety (GPSD)

DG MOVE

Unit C.4- Rail Safety and Interoperability

- Interoperability of Rail Systems (IRS)

The HAS project as a Service

Service to the:

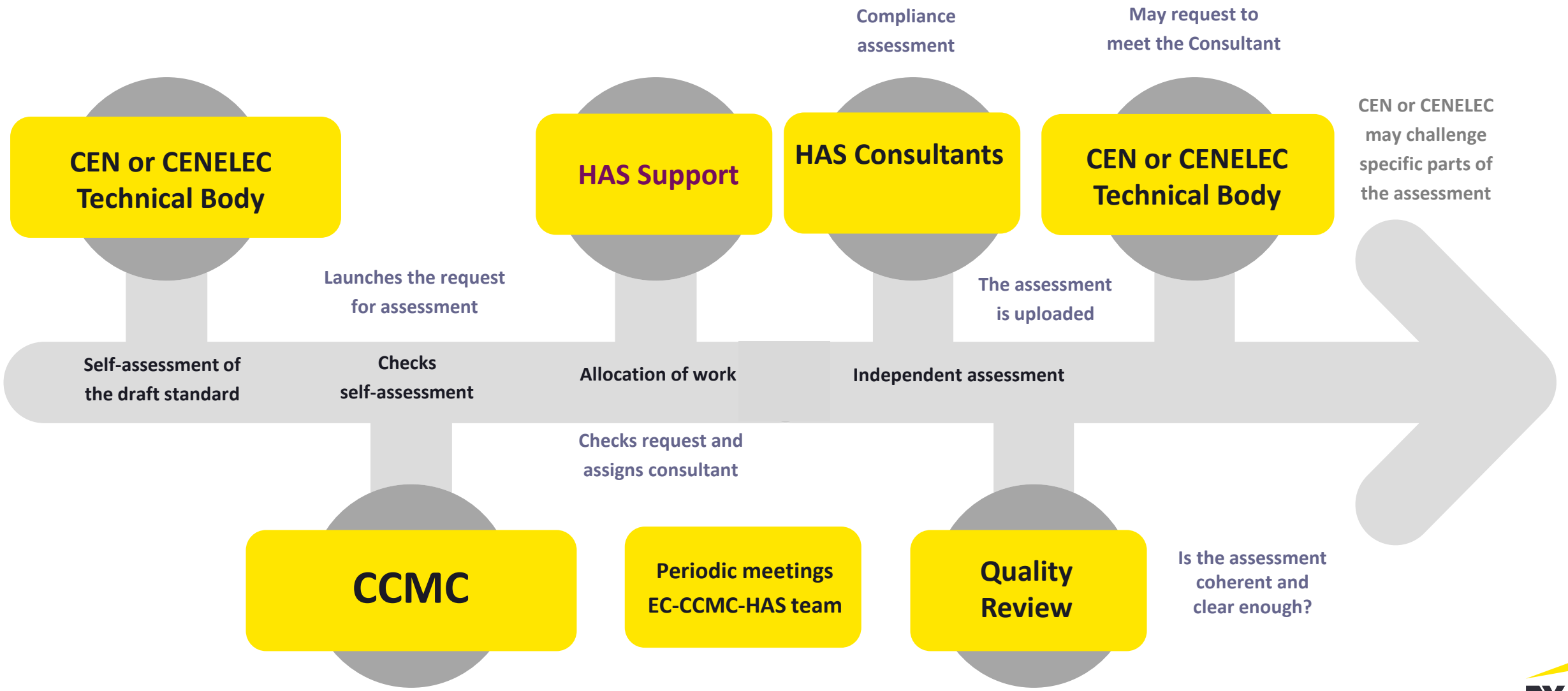
- European Commission
- Technical bodies of the European Standardisation Organisations

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

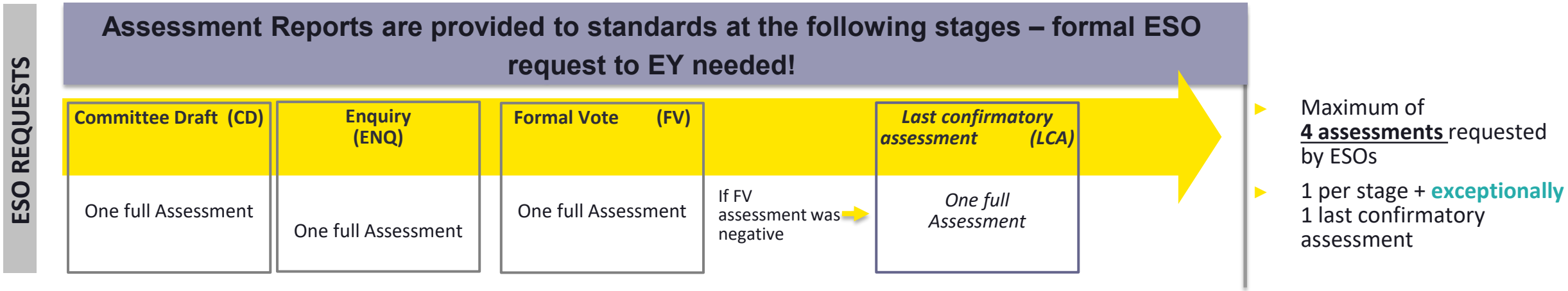
Main features:

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

HAS system process overview



When to request and assessment and what to expect?



Recap on role of HAS Consultants:

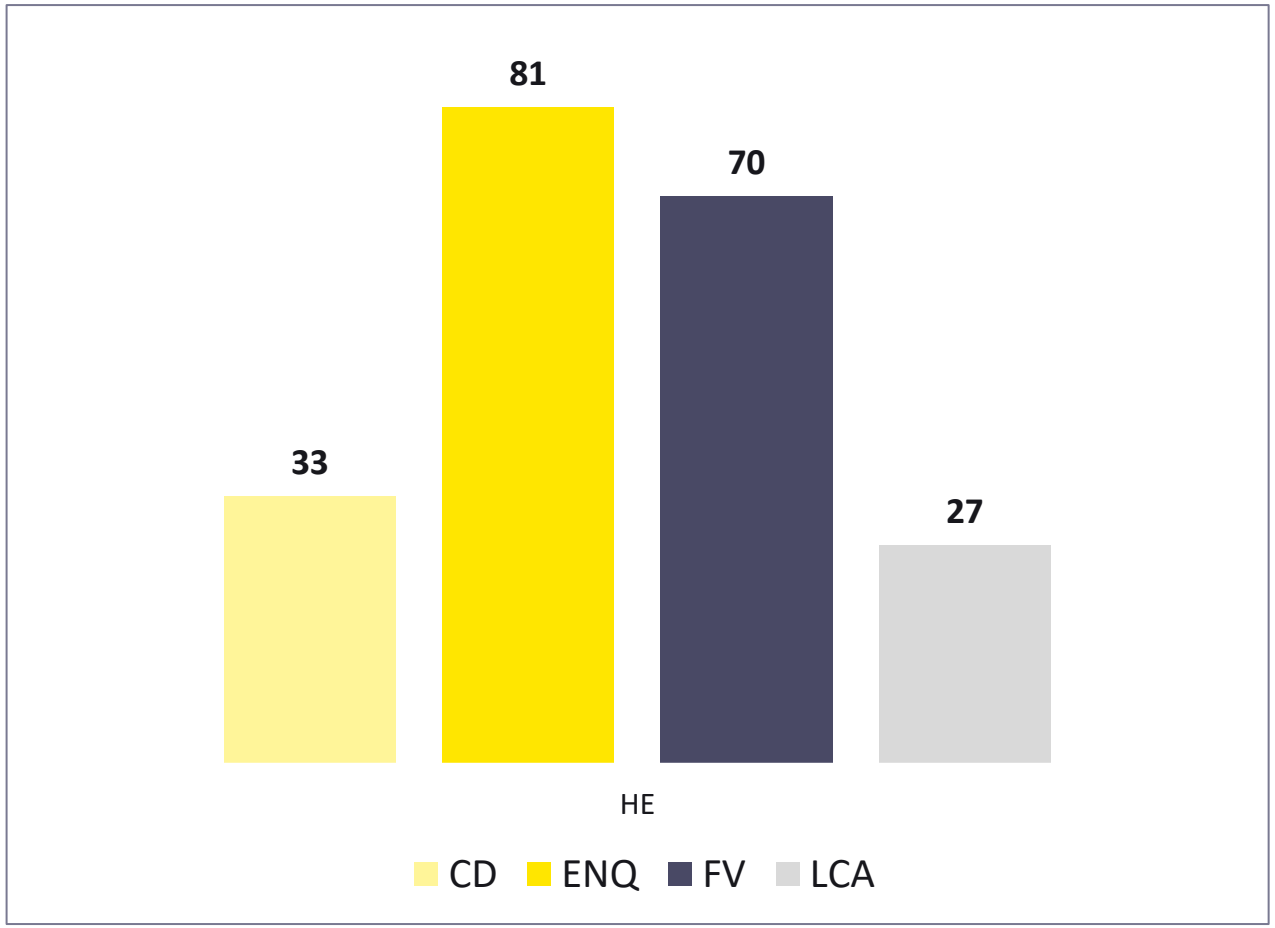
- Perform verification and assessment tasks
- Work in support of but do not represent the Commission
- Convey the Commission's positions to the ESOs or their technical bodies
- Are not allowed to modify their report(s) or assess revised documents during meetings with TCs
- Do not contribute to the standards development process

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

Update on the progress in the assessment work

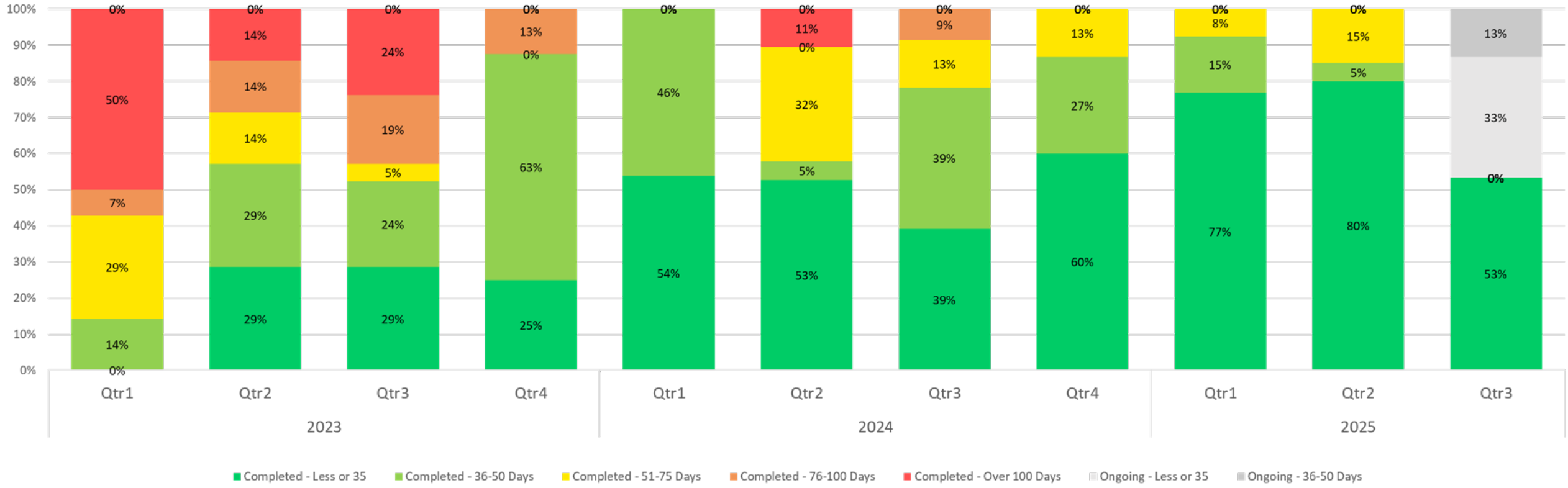
Building a better working world

Stages of assessment requests

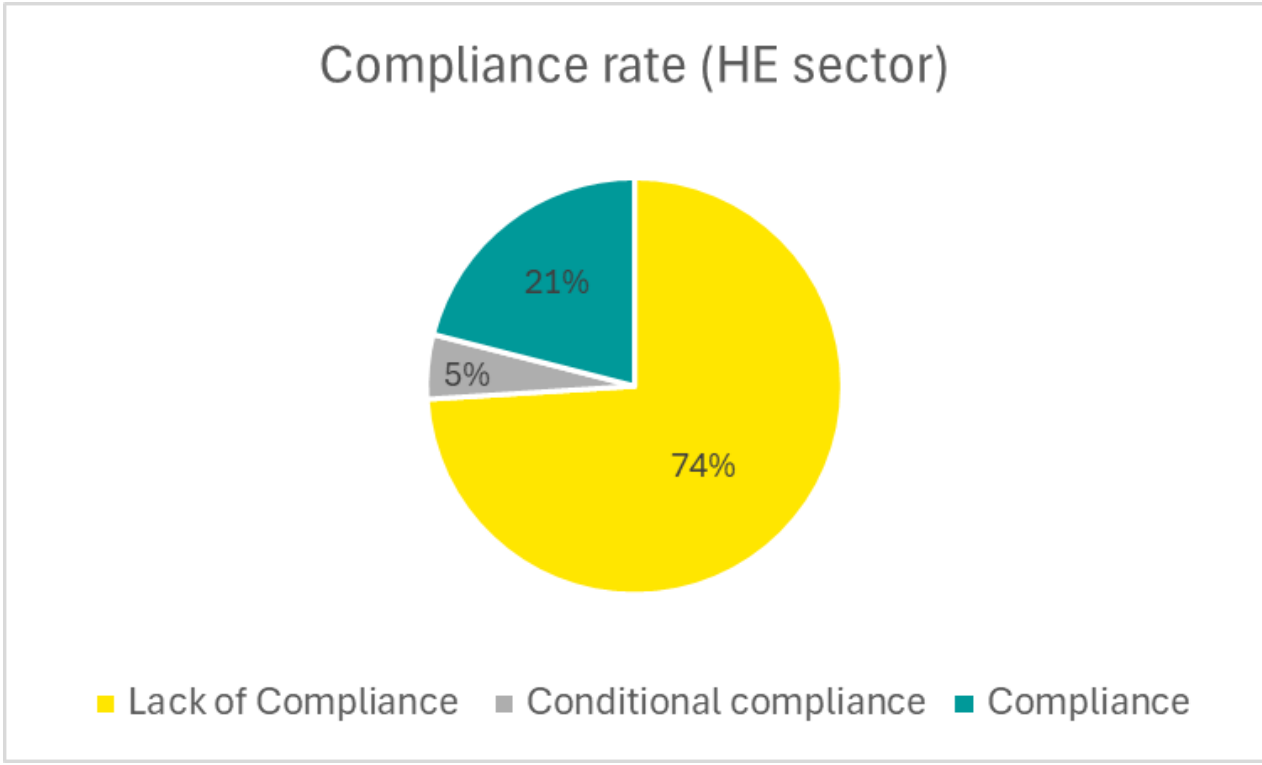


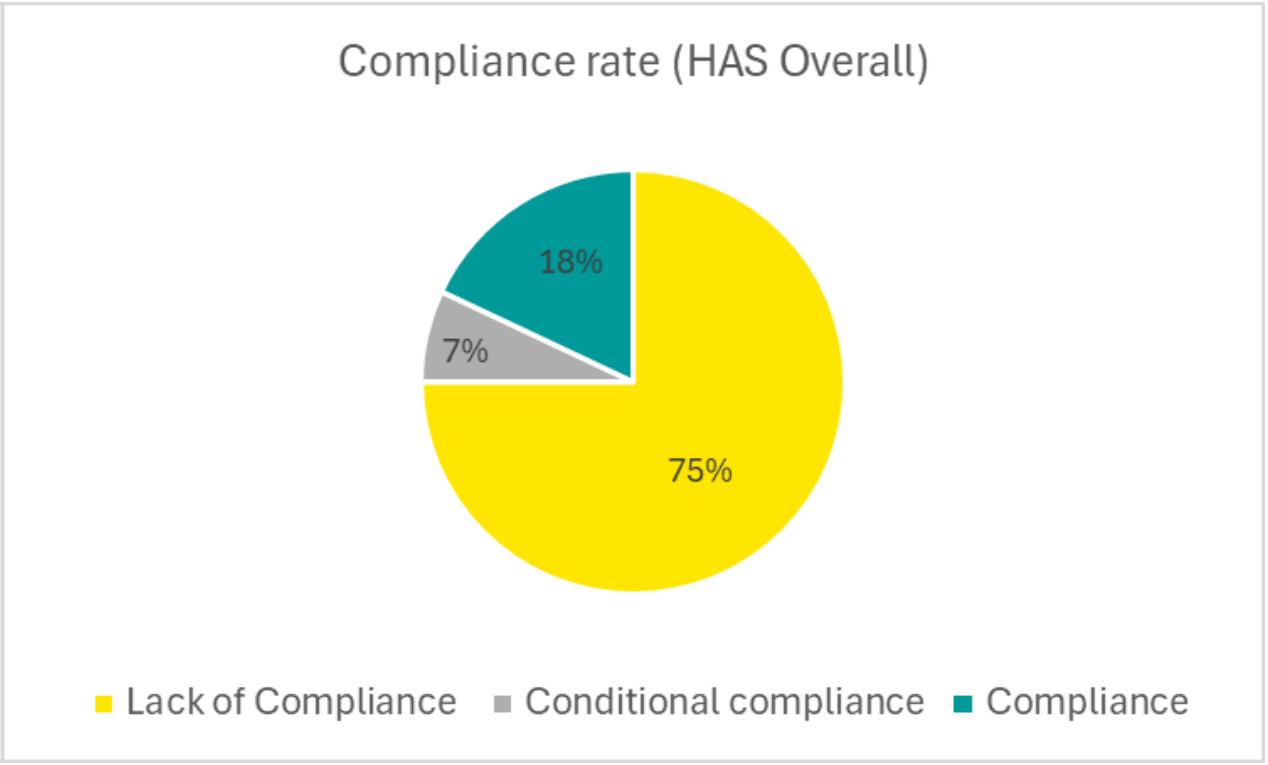
- TCs are **encouraged** to requests an assessment at the **early stages** of drafting (CD and ENQ) to increase the compliance rate at later assessment stages
- In case of lack of compliance, TCs must wait until the **next stage** to submit a new request
- In between two assessments, TCs are encouraged to **request a meeting** with HAS Consultants (to receive clarification on comments received)
- HAS Consultants are **not allowed to modify their report(s)** or assess revised documents during meetings with TCs

Timeliness of assessments (HE Sector)



Assessment compliance outcomes*

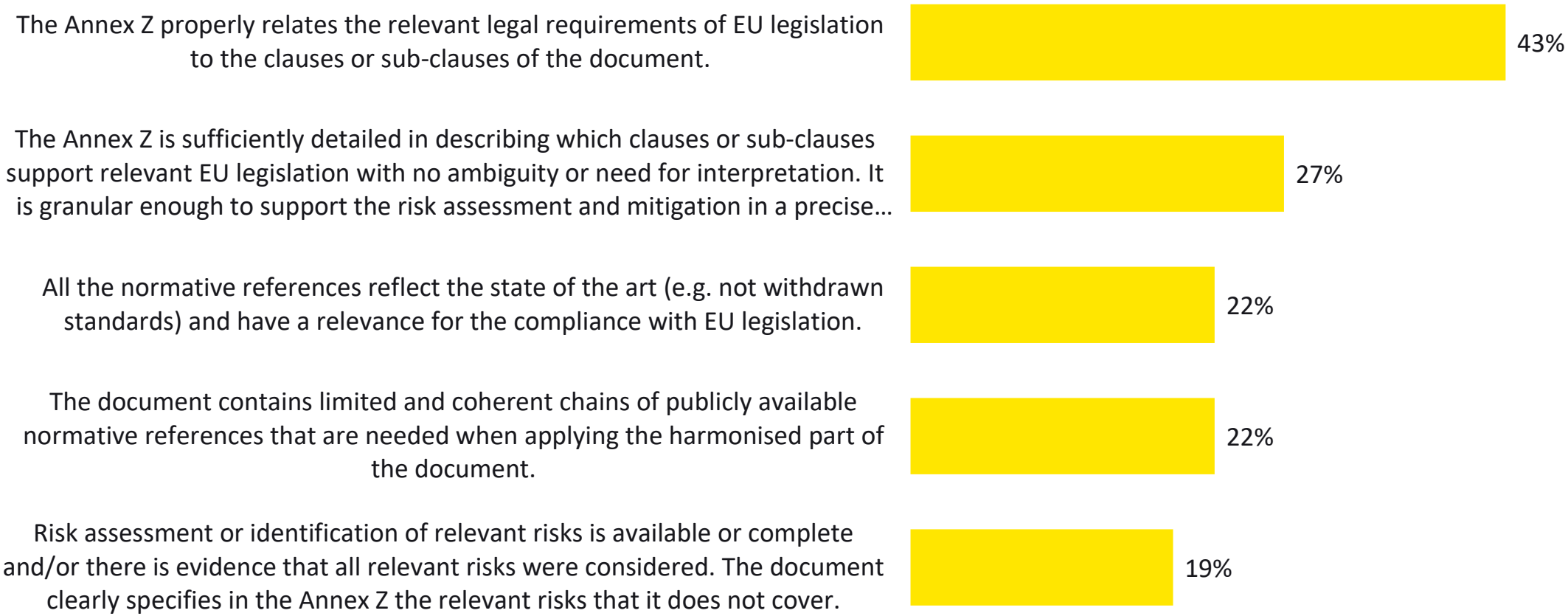




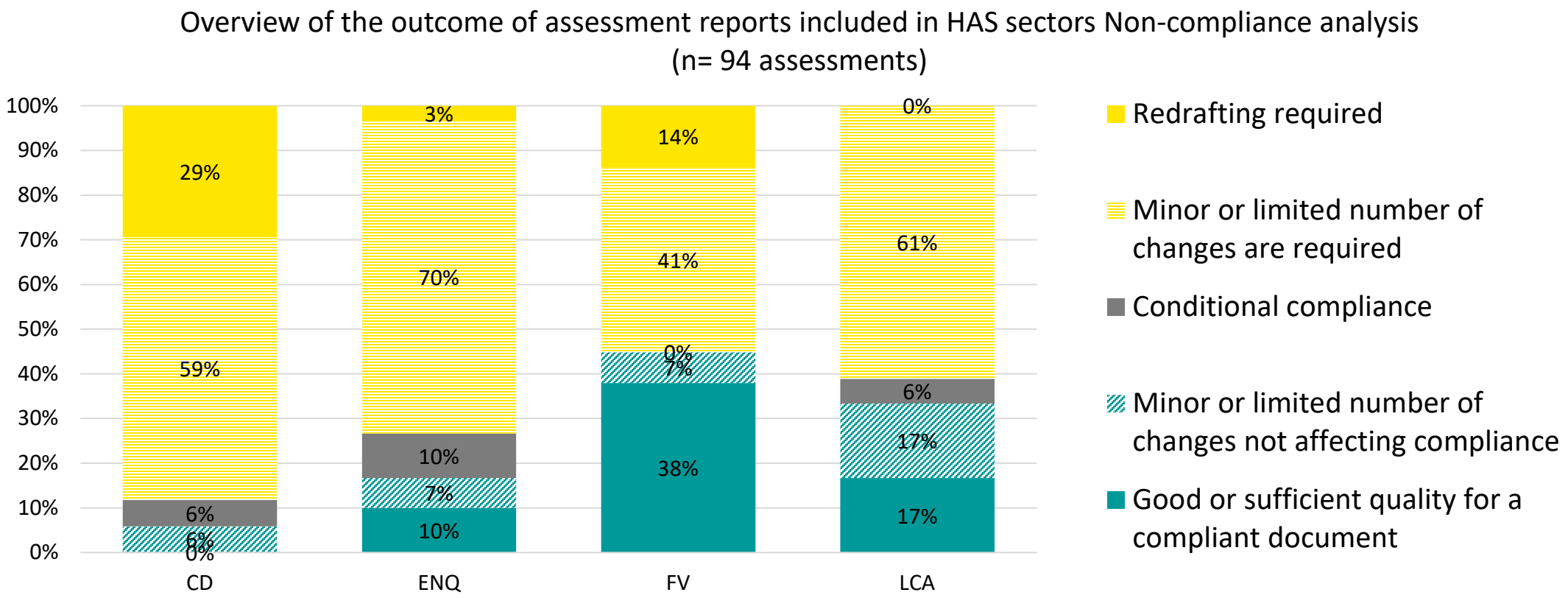
*Based on 94 assessments completed since October 2023 (using new assessment template).

Top 5 findings leading to Lack of Compliance in HE sector

Requirements **not met**:



Share of outcomes by stage of assessment requests in HE sector



*Based on 18 assessments at LCA, 29 at FV, 31 at ENQ, and 18 at CD stages completed since October 2023 (using new assessment template)

Continuous improvement of the HAS system

We learn everyday and have taken a range of steps to further improve the HAS system

- AVOID CHANGING CONSULTANTS BETWEEN DIFFERENT ASSESSMENTS AS MUCH AS POSSIBLE
- IMPROVED SPEED OF RESOLUTION WHEN DISCREPANCIES IN ASSESSMENTS
- IMPROVED COORDINATION BETWEEN CONSULTANTS
- INCREASED CONSISTENCY THROUGH GUIDANCE AND TRAINING
- STREAMLINED THE PROCESS TO REQUEST MEETINGS WITH CONSULTANTS
- INCREASING COMMUNICATION AND MUTUAL LEARNING WITH TECHNICAL COMMITTEES

Meeting requests – best practices

- Meetings adhering the below criteria are encouraged
- Meeting requests should be submitted minimum 4 weeks prior to the meeting date
- A full agenda of the meeting should be provided to allow the HAS consultants to prepare
- Only meetings linked to a previous assessment are allowed under the HAS project
- Physical meetings are possible but subject to approval by HAS Consultants
- Link to meeting tool: **Link**

Reminder on the role of HAS consultants during meetings with TCs

What a HAS Consultant can do

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

*Consultants should check if the harmonised standards are compliant with the legislation. Technical comments on elements not linked through Annex Z are considered as recommendations.

What a HAS Consultant cannot do

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

Thank you!

If you have any queries or comments, please reach out to:

has.support@be.ey.com

Best practices and recurring issues

Christoph Kiesselbach (HAS Consultant)

Daniele Lioi (HAS Consultant)

Digression: Use of standards in GSPR checklist

- Requirement for manufacturer's Technical Documentation in Annex II: Demonstration of conformity for each applicable General Safety and Performance Requirement (GSPR) with method and documented evidence.
- Common Specifications and harmonised standards provide solutions with presumption of conformity.
- Usually documented in table, e.g.:

GSPR	Method used to demonstrate conformity (or reason why n/a)	Solution applied (CS, harmonised standard or other)	Documented evidence

- It is essential that the Annex Z provides sufficient information to clearly identify which methods are suitable for which GSPR, what parts of the GSPR are addressed and what documented evidence is required – only then the presumption of conformity is provided.
- The following examples all have in common that this connection is unclear, leading to confusion in the use of the standard by the manufacturer and subsequent review by the notified body.

Major topics

- Definitions of terms in a standard
- Specificity of a Clause referenced for GSPRs
- Normative references
- Administrative

Definitions of terms in a standard: Status

- The following section was integrated into the Annex Z template to oblige with requirements set out in Annex III of the standardisation request:

  “Where a definition in a harmonised standard differs from a definition of the same term set out in Regulation XXX, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.”

- However, in many cases there is no indication of differences in definitions, e.g. in a separate table.
- Differences in definitions should be included in Annex Z in a consistent way.

Definitions of terms in a standard: Future solution?

- Where a term defined in European standard is also defined in the regulations, the correspondence and difference between the definitions is indicated in Table Z.X and the definition as made in those regulations prevails;
- Where a term defined in this European standard is not defined in the regulations and is also not legally relevant, the term as defined in the standard applies without any different meaning.
- *Practical examples on how the differences were explained in recent assessments:*

Term used in this EN	Clause / sub-clause where this term is defined in this EN	Article in (EU) 2017/745 or (EU) 2017/746 that defines or uses this term	Differences / Consequences
Clinical Investigations			Both definitions are substantially equivalent. The definition in this document specifies an investigation undertaken to assess the clinical performance, effectiveness or safety of a medical device. In the Regulation, the definition is an investigation undertaken to assess the safety or performance of a device. **Effectiveness is defined in this document** and introduced as the term is used in regulations outside Europe.
Risk			Identical definitions in MDR and this standard, however, **MDR** has a **narrower** meaning of the term “harm” used in the definition for risk, see above, **which prevails for use of this EN under the MDR.**

Specificity of a Clause referenced for GSPRs: Chapter I

Annex ZA cites GSPR from Chapter I:

- GSPRs in Chapter I of Annex I are very broad and usually not addressed by a single standard
- E.g. every harmonised standard to some degree contributes to GSPR 1 by providing information about the generally acknowledged state of the art

- A consistent solution should be found for these GSPRs to be included in Annex ZA where the standard only covers these GSPRs to a very limited degree.
- Exceptions could be standards addressing procedural issues e.g. EN ISO 14971 for risk management processes.

Specificity of a Clause referenced for GSPRs: No match

Clause does not match GSPR, example:

- Statement in Clause:
  "*The information supplied shall include **sufficient instructions** on the use of the indicator system to enable correct interpretation of the test results.*"
- Requirement in GSPR 23.1 (a):
  "*The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.*"
- Claim in draft Annex ZA:
  GSPR 23.1 is covered.

➢ No technical specification to address this requirement of 23.1 (a) is provided. For this reason, the GSPR should be considered not addressed by this Clause.

Specificity of a Clause referenced for GSPRs: Insufficient

Clause does not provide sufficient technical solution to address GSPR, example:

- Statement in Clause:
  "*the procedures of EN 62366-1:2015 shall be applied to improve safety and the usability of the equipment and to identify related risks*"
- Requirement in GSPR 21.3:
  "*The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.*"
- Claim in draft Annex ZA:
  GSPR 21.3 is covered.

- In this case, the Clause does not provide any technical solution to address the related GSPR but only references another (currently not harmonised) standard.

Specificity of a Clause referenced for GSPRs: Too broad

Broad referencing of Clauses for specific topics / requirement of the standard do not cover the very specific Essential Requirement: Example

- GSPR 6 is claimed to be covered by ‘all’ the clauses and subclauses of the standard and there is no qualifying comment to describe the extent of coverage.
- Requirement in GSPR 6:
  “The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.”

➢ This GSPR is related to stresses that can occur during normal use during the lifetime of the device. Very few of the clauses and subclause relate to such – the coverage of this GSPR should be reviewed.

➢ In some cases, broad references can not be avoided (e.g. standards for sterilization processes)

Specificity of a Clause referenced for GSPRs: Unclear

Coverage of a clause unclear

- The cited Clause(s) for GSPR 10.1 are stated to “cover” the GSPR. However, they include some, but not all chemical and physical specifications applicable
- Requirement in GSPR 10.1 (h):
  “Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:
  (h) the confirmation that the device meets any defined chemical and/or physical specifications.”

- The requirement is addressed with respect to defined chemical and/or physical performance specifications. From the remark/note section of Table ZA.1, it should be clear whether the GSPRs are fully or partially covered.
- If partially covered, it should be stated in a clear, consistent way which requirements are covered, and which are not.

Scope of addressed GSPRs is minimal

GSPRs that could be addressed are left out, example

- Draft standard for respiratory infection protection devices references a single Clause for GSPR 11.1, that deals with bioburden requirements. No other Clause and no other GSPR is cited.
- Requirement GSPR 11.1:
  "Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

  (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,
  (b) allow easy and safe handling,
  (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use,
  (d) prevent microbial contamination of the device or its content such as specimens or fluids."

➢ The standard covers more requirements than just a limited aspect of a single GSPR. Leaving them out to avoid confrontation is not helpful (the resolution was to include an overly broad reference to GSPR 1, citing the whole standard; see previous slide). In some cases, limited references can not be avoided.

Normative references

• Undated references • Obsolete references • References to drafts • References to technical reports		Keep undated references when an appropriate justification is provided: The European Annex ZA includes the corresponding dated versions of those standards, applicable at the time of publication of the international standard version.
• Reference to complete body of a Standard		Implies that the whole standard satisfies requirements of a harmonized standard. Elements that affect the compliance can be detected in the cited standard and affect overall compliance.
• The use of the mentioned standards is required only “if applicable” or there is a requirement using “equivalent specifications”.		Creates an arbitrary choice for who decides to apply the Harmonized Standard. Users should know which specification applies to address EU legal requirements and no room for arbitrary choices should be included in a clause to grant presumption of conformity.

Administrative

- <u>The package submitted for the assessment is not complete/incorrect</u>
  - E.g. only drafted annex ZZ and ZA were provided in the package together with previous annexes (vs 93/42)
  - Naming of drafts and published standards is not clear
  - Only ISO/IEC version sent, may cause confusion
  - Old version of the draft sent, not the revised version

- <u>Addressing changes from the previous assessments</u>
  - Changes from previously evaluated draft not clear
  - Changes after comments, including HAS comments, change the previous assessment results

Key points

Topic	Issue	Improvement
Definitions of terms in a standard		Carefully check definitions in the Standard and verify if they overlap with the MDR, write appropriate justification in Table ZA.3 with clear statement which one prevails
Specificity of a Clause referenced for GSPRs	Clause does not match GSPR	Check all the content of the GSPR to match the clause appropriately
	Clause does not provide sufficient technical solution to address GSPR	Additional clarifications / technical solutions or elimination of the clause
	Broad referencing of Clauses for specific topics	Insert a qualifying comment that describes the extent of coverage of this GSPR related to stresses that can occur during the lifetime of the device; Only list clauses and subclauses in the middle column that are directly relevant to the coverage of this GSPR.

Key points

Topic	Issue	Improvement
Specificity of a Clause referenced for GSPRs	Coverage of a clause unclear	Clearly state whether the clause partially or fully covers a GSPR
	GSPRs that could be addressed are left out (sometimes only leaving single aspects of a single GSPR)	Reference all GSPRs that are supported by the standard. Having a harmonised standard that formally fulfills only a minimal part of the GSPRs is not helpful and misleading.
Normative references	Undated references	Use Annex ZA Table to indicate the corresponding dated versions of those undated standards, applicable at the time of publication of the international standard version.
	Reference to complete body of a Standard	In principle, better to avoid it unless it is clear which part of the Standard are to be used.
	Statements ”only if applicable” or using “equivalent specifications”.	Try to avoid it Or create a clear statement to avoid arbitrary choices

Key points

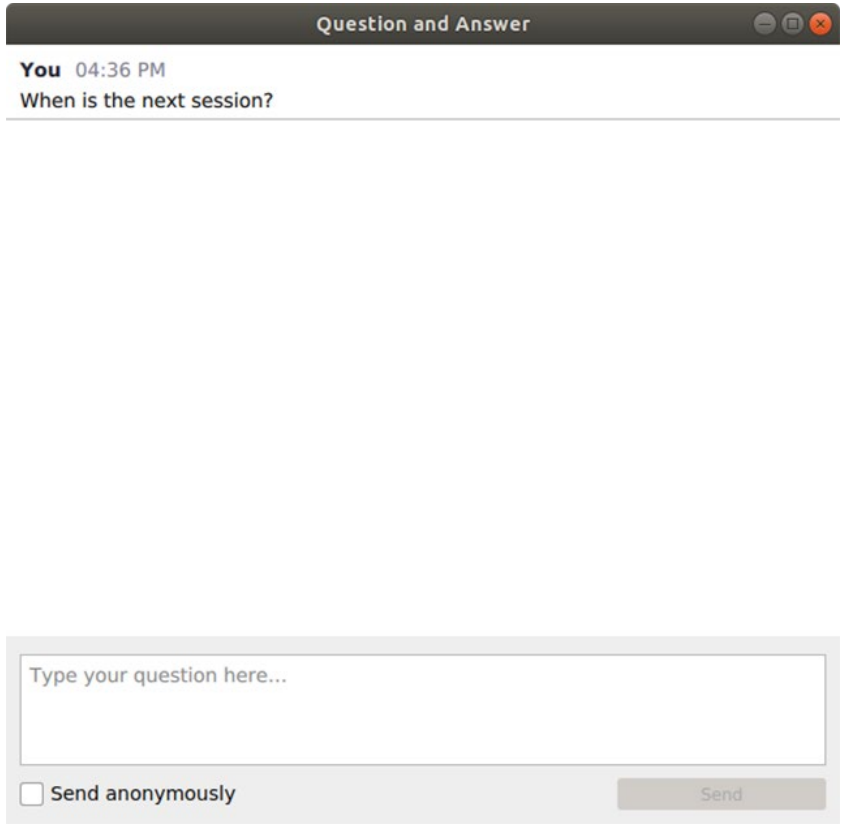
Topic	Issue	Improvement
Administrative	The package submitted for the assessment is not complete/incorrect	Additional checks on the documentation
	Changes from previously evaluated draft not clear	Best way would be to highlight changes related to initial HAS comments
	Changes after comments, including HAS comments, change the previous assessment results	this is not possible to fully solve due to the development process and comments from participants on the standard development, but more care can be taken if the issue is clear to the drafters and participants

Q&A session

Your feedback

Question time

- Use the Q&A panel to submit your questions



Thank you for your attention

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Frédéric Mlanao