European Standardization Organizations

Webinar *'Drafting for compliance: best practices in standards in support of the Personal Protective Equipment Regulation'*

We start at 10:00 CET

Your webinar moderator

Els Somers

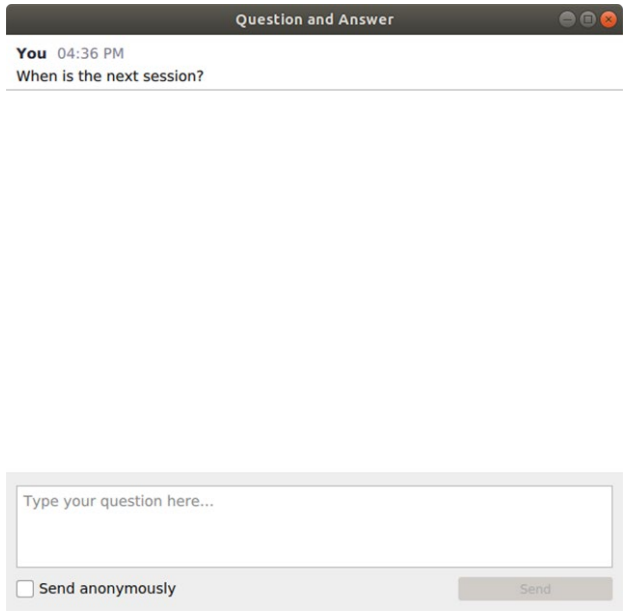
Project Manager

Public Relations

esomers@cencenelec.eu

Get the most out of the webinar today

- Use the Q&A panel to submit your questions



- Talk about us on LinkedIn, Bluesky or Instagram #training4standards @Standards4EU

Opening remarks by the European Commission

Ivan ARIAS ROLDAN, European Commission

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 (OJEU).**

Links

- European standards - Internal Market, Industry, Entrepreneurship and SMEs
  - Vademecum on European standardisation - Internal Market, Industry, Entrepreneurship and SMEs
- Personal protective equipment (PPE) - Internal Market, Industry, Entrepreneurship and SMEs
  - Regulation - 2016/425 - EN - EUR-Lex
  - PPE Regulation (EU) 2016/425 Guidelines
  - Harmonised standards under the PPER
- European Commission Standardisation Requests

Thank you

Your speakers today

Jennifer OGBONNA

jogbonna@cencenelec.eu

Frédéric MLANAO

fmlanao@cencenelec.eu

Key development processes and drafting reminders

Frédéric Mlanao, Account Manager at CEN and CENELEC

Innovative Process – homegrown hEN

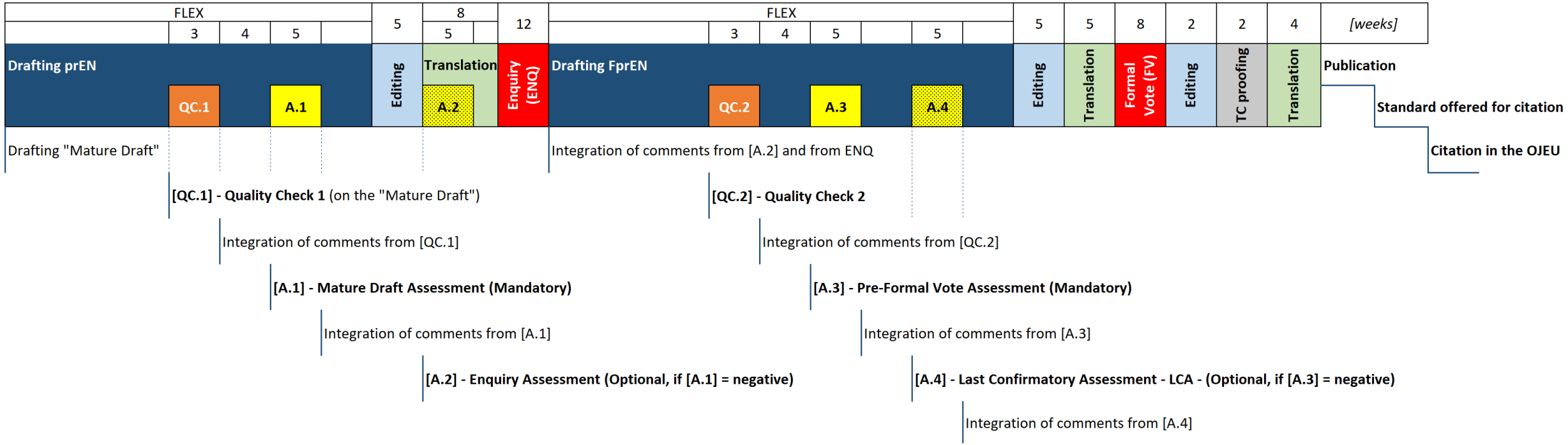
Target: To increase the number of “compliant” assessments and, in fine, the number of standards cited in the OJEU.

Innovative process based on 2 main pillars:

- Mature draft concept
  - Draft ready for ENQ
  - Mature draft assessment **mandatory**
- 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

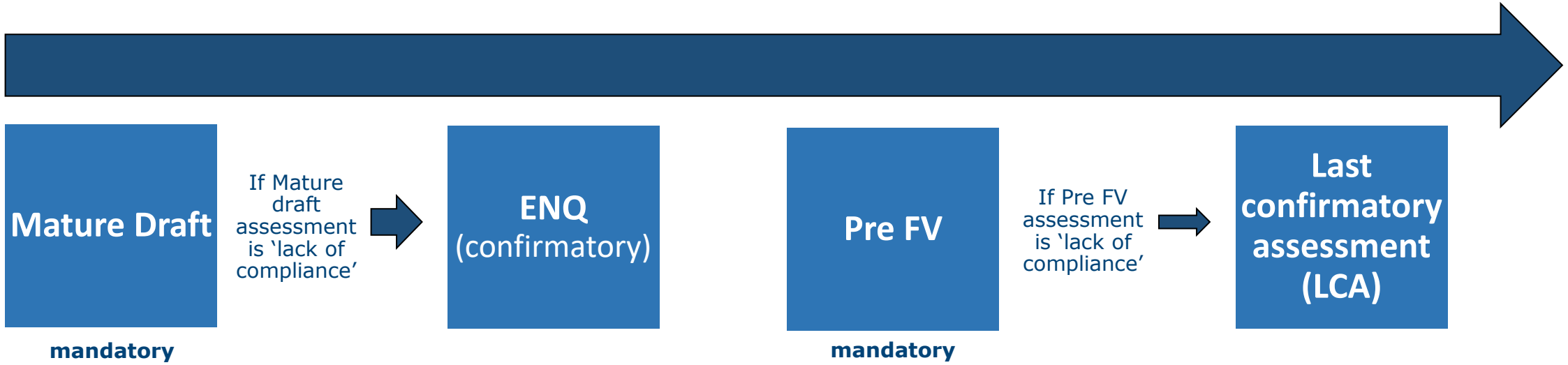


Innovative Process – homegrown hEN

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 ensures that the “Checklist for hEN” is filled-in
- 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

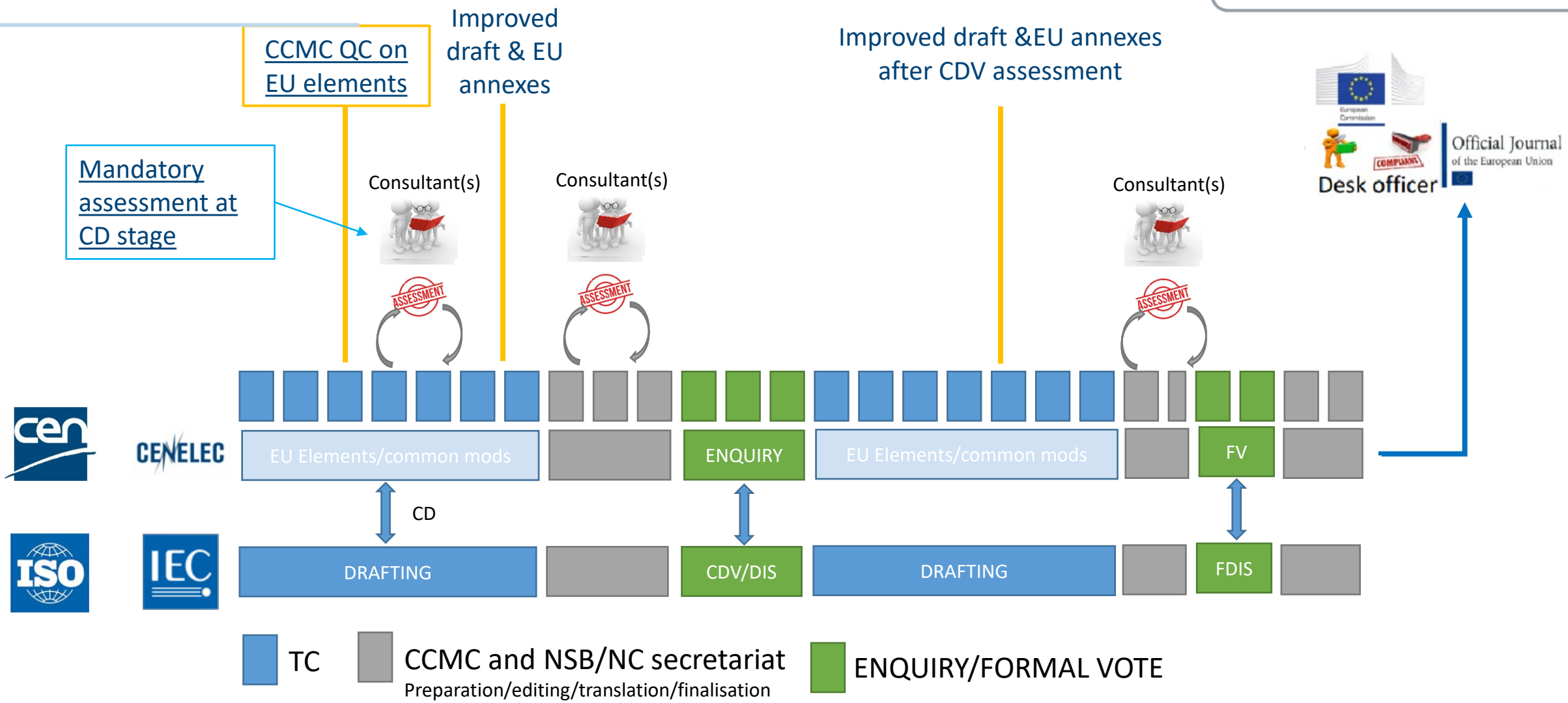
The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

‘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

- 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

Useful Links, CENELEC

- CEN webinar 'Drafting harmonized standards - IR3 rules, requirements and normative references'
- Webpage: Drafting European standards for citation in the OJEU
- Webpage: Drafting EN IEC 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

Requirements in the PPE Standardization Request Reminders

Jennifer Ogbonna, Project Manager at CEN and CENELEC

Legal Requirement of the PPE Standardization Request

- Requirement is laid down in Point 2, Part A of Annex II to the PPE Standardization Request (C(2020) 7924 final))

  'When a harmonized standard does not cover all the essential health and safety requirements, which are applicable to the PPE falling under its scope, the standard shall indicate the essential health and safety requirements applicable to those PPE that are not covered by it '

- In addition, the European Commission requests that Technical Committees list **all** Essential Health and Safety Requirements of the PPE Regulation in **Column 1 of Annex ZA**, irrespective of whether they are covered, not covered, or not applicable to the standard, in order to ensure that all requirements have been duly considered.

Legal Requirement of the PPE Standardization Request

- List all EHSR in first column of Annex ZA in numerical order:

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirements (ERs) of Regulation (EU) 2016/425	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.1.1 Ergonomics		
1.1.2.1 Optimum level of protection		
1.1.2.2 Classes of protection appropriate to different levels of risk		
1.2.1 Absence of risks and other 'inherent' nuisance factors		
1.2.1.1 Suitable constituent materials		
1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user		
1.2.1.3 Maximum permissible user impediment		
1.3.1 Adaptation of PPE to user morphology		
1.3.2 Lightness and strength		
1.3.3 Compatibility of different types of PPE intended for simultaneous use		
1.3.4 Protective clothing containing removable protectors		
1.4 Manufacturer's instructions and information		
2.1 PPE incorporating adjustment systems		
2.2 PPE enclosing the parts of the body to be protected		
2.3 PPE for the face, eyes and respiratory system		
2.4 PPE subject to ageing		
2.5 PPE which may be caught up during use		
2.6 PPE for use in potentially explosive		

2.1 PPE incorporating adjustment systems		
2.2 PPE enclosing the parts of the body to be protected		
2.3 PPE for the face, eyes and respiratory system		
2.4 PPE subject to ageing		
2.5 PPE which may be caught up during use		
2.6 PPE for use in potentially explosive atmospheres		
2.7 PPE intended for rapid intervention or to be put on or removed rapidly		
2.8 PPE for intervention in very dangerous situations		
2.9 PPE incorporating components which can be adjusted or removed by the user		
2.10 PPE for connection to complementary equipment external to the PPE		

Legal Requirement of the PPE Standardization Request

- **Case 1**:
  - Column 1 - EHSRs applicable to your product and covered by the standard
  - Column 2 -For those EHSRs that are applicable indicate all the clauses of the standards with the highest granularity
  - Example below:

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirements (ERs) of Regulation (EU) 2016/425	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.1.1 Ergonomics		
1.1.2.1 Optimum level of protection		
1.1.2.2 Classes of protection appropriate to different levels of risk	6.1.2	
1.2.1 Absence of risks and other 'inherent' nuisance factors		
1.2.1.1 Suitable constituent materials		
1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user		

Legal Requirement of the PPE Standardization Request

- **Case 2**:
  - Column 1 - EHSR applicable to your product, but not covered by the standard
  - Column 2 - leave it empty
  - Column 3 - indicate "**not covered**"

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirements (ERs) of Regulation (EU) 2016/425	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.1.1 Ergonomics		not covered
1.1.2.1 Optimum level of protection		
1.1.2.2 Classes of protection appropriate to different levels of risk		
1.2.1 Absence of risks and other 'inherent' nuisance factors		
1.2.1.1 Suitable constituent materials		
1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user		
1.2.1.3 Maximum permissible user impediment		
1.3.1 Adaptation of PPE to user morphology		
1.3.2 Lightness and strength		
1.3.3 Compatibility of different types of PPE intended for simultaneous use		

Legal Requirement of the PPE Standardization Request

- **Case 3 (EC request)**:
  - Column 1 - EHSR not applicable to your product (not covered in the standard)
  - Column 2 - leave it empty
  - Column 3 - indicate **"not applicable"**

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirements (ERs) of Regulation (EU) 2016/425	Clause(s)/subclause(s) of this EN	Remarks/Notes
1.1.1 Ergonomics		
1.1.2.1 Optimum level of protection		
1.1.2.2 Classes of protection appropriate to different levels of risk		
1.2.1 Absence of risks and other 'inherent' nuisance factors		
1.2.1.1 Suitable constituent materials		
1.2.1.2 Satisfactory surface condition of all PPE parts in contact with the user		
1.2.1.3 Maximum permissible user impediment		
1.3.1 Adaptation of PPE to user morphology		
1.3.2 Lightness and strength		
1.3.3 Compatibility of different types of PPE intended for simultaneous use		
1.3.4 Protective clothing containing removable protectors		not applicable

Article 4 Requirement of PPE Standardization Request

- Article 4 of the PPE Standardization Request (C(2020) 7924 final))

Article 4
Harmonised standards

CEN and Cenelec shall include in each harmonised standard a clear and precise description of the relationship between its content and the corresponding essential health and safety requirements set out in Annex II to Regulation (EU) 2016/425 that it aims to cover. Each harmonised standard developed on the basis of the request referred to in Article 1 of this Decision shall refer to this Decision.

CEN and Cenelec shall include in each revised standard information on significant changes that were introduced in that standard.

CEN and Cenelec shall provide the Commission with the titles of the requested harmonised standards in all the official languages of the Union.

- These changes are to be indicated in the European Foreword

Article 4 Requirement of PPE Standardization Request

- This information is essential to understand the **impact of the modifications to the products on the market** :
  - manufacturers to have a first idea on the need to redesign their products
  - notified bodies to assess the need of reviewing the existing EU-type examination certificates
  - market surveillance authorities to properly assess the risks of the products on the market, the compliance of which has not been assessed with the revised standard
  - Commission to understand the overall impact and to assess any transition period for the superseded standard

Article 4 Requirement of PPE Standardization Request

- Requirement is also in Point 2.10.4 of Part III of the Vademecum on European Standardization and in section 14 of the PPER guidelines when clarifying the 'Validity of an EU type-examination certificate and revision of harmonized standards'

- This requirement is in line with CEN-CENELEC Internal Regulations Part 3, clause 12.5.2, point c as shown below:

c) a statement that the document supersedes other documents in whole or in part, and a statement of significant changes with respect to the previous edition of the document;

EXAMPLE 3

This document supersedes EN 12341:2014.

The main changes compared with EN 12341:2014 are as follows:

– symbols have been harmonized with those used in ISO 3233-1 and ISO 3233-2;
– determination of dry film thickness has been added;

[...]

- Guidance - Identification of significant technical changes in revised European Standards

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 and 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

Julia Migda

HAS Operations Executor

Hanna Falkiewicz

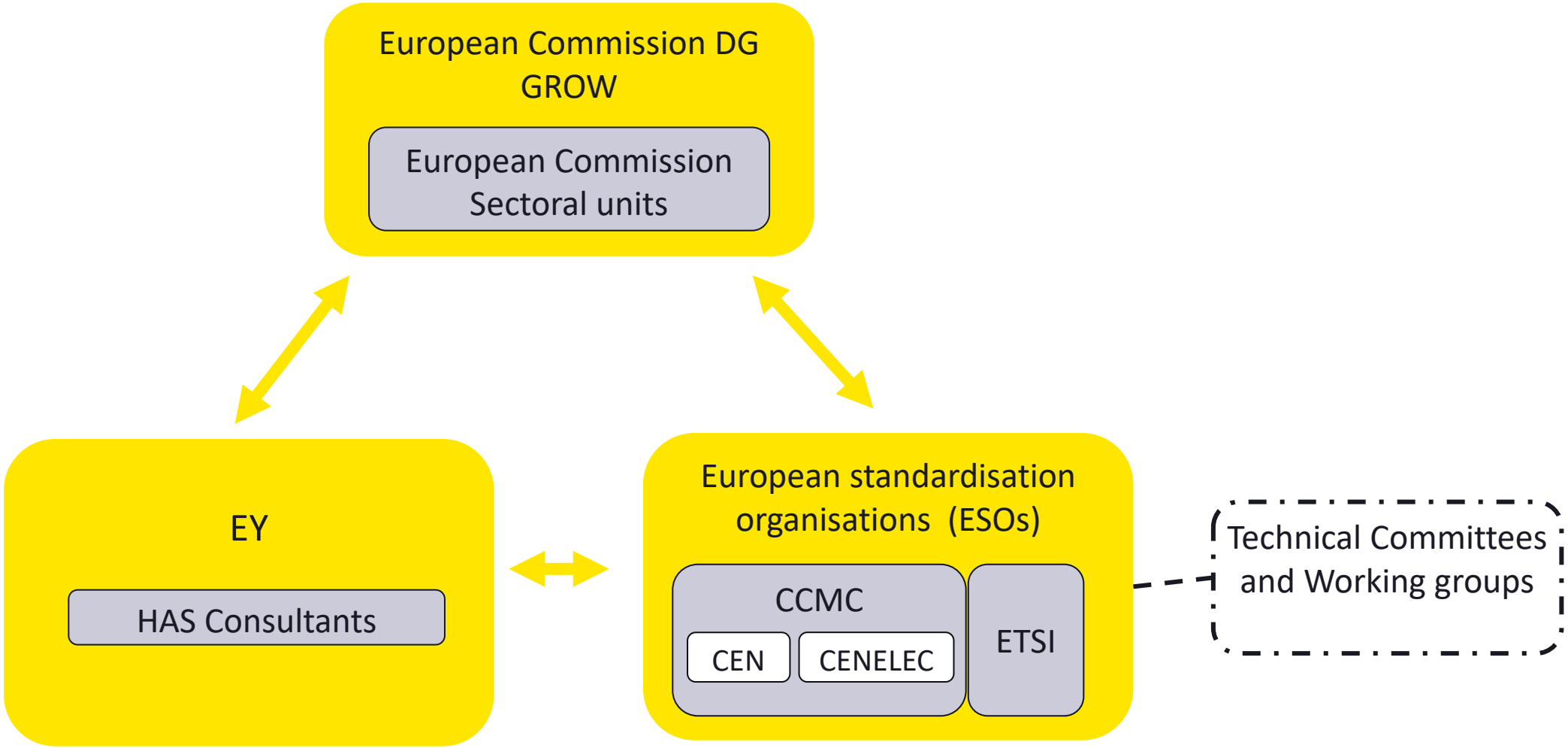
Invoicing Coordinator

HAS Consultants (PPER)

Adam Poscik

Jose Bahima Toha

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)
- Lifts (LD)
- Electro-magnetic Compatibility (EMC)
- Radio Equipment (RED)
- Pressure equipment and Simple Pressure Vessels (PED&SPVD)
- Recreational Craft (RCD)
- 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 (GPSR)

DG MOVE

Unit C.4- Rail Safety and Interoperability

- Interoperability of Rail Systems (IRS)

The HAS project as a Service

Service to the:

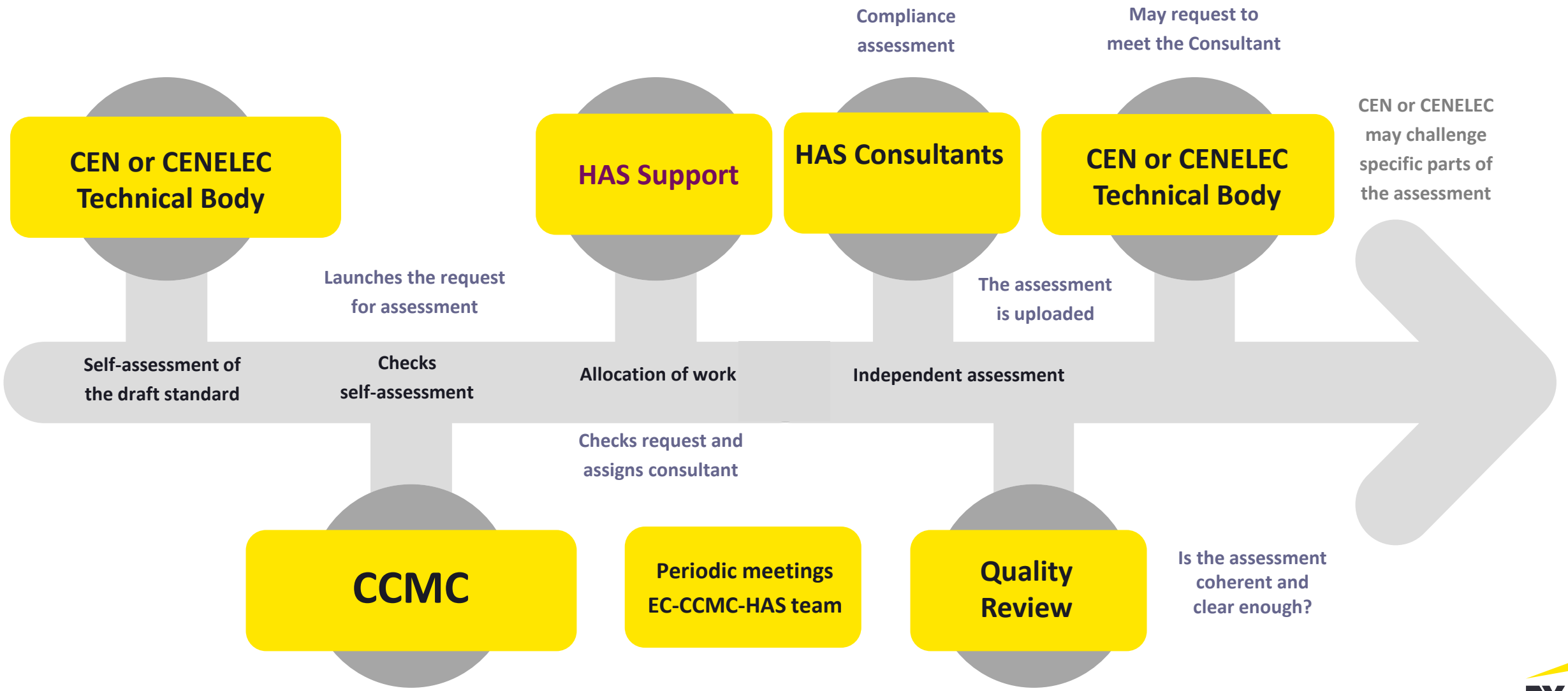
- European Commission
- Technical bodies of the European Standardisation Organisations

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

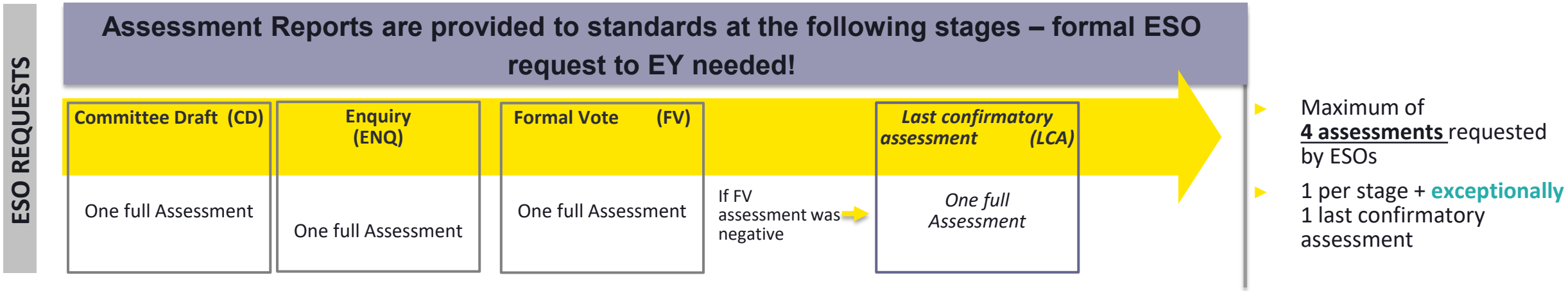
Main features:

- 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:

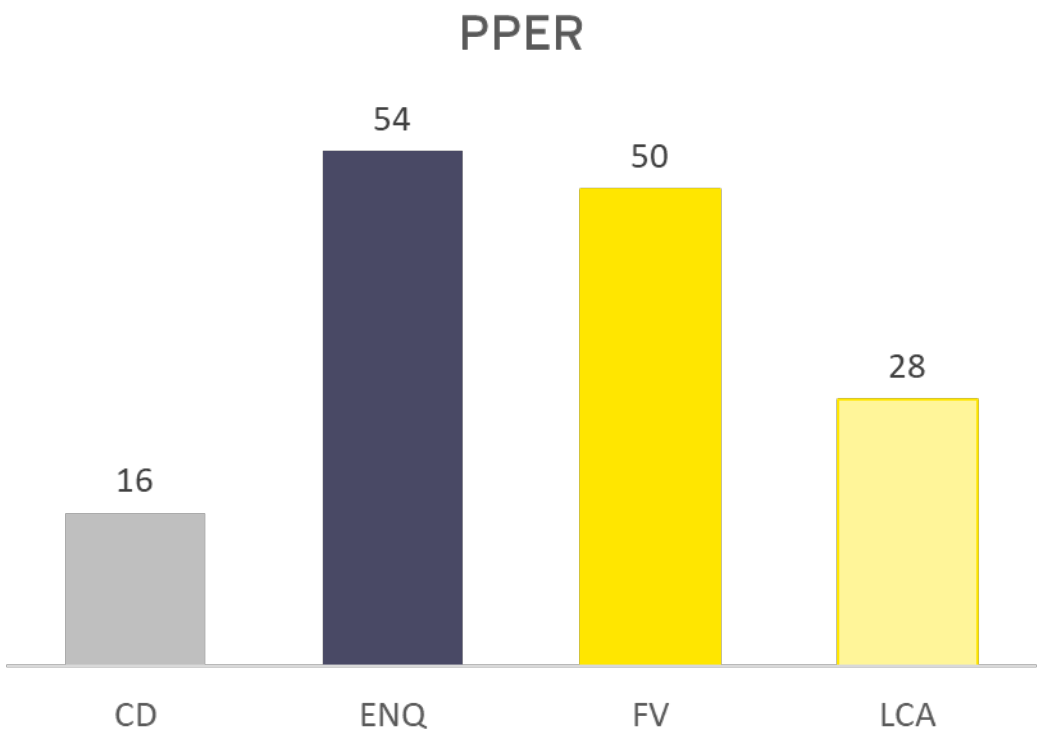
- Perform verification and assessment tasks
- Work in support of but do not represent the Commission
- Convey the Commission's positions to the ESOs or their technical bodies
- Are not allowed to modify their report(s) or assess revised documents during meetings with TCs
- Do not contribute to the standards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

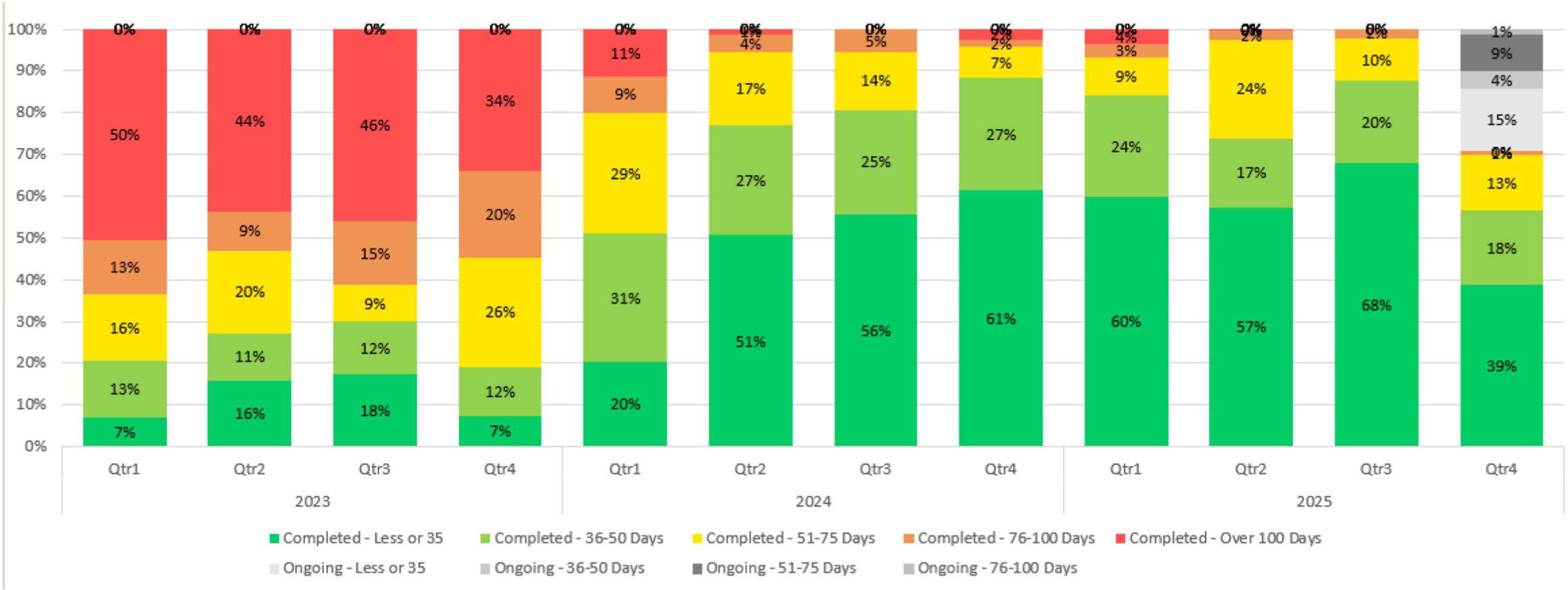
Building a better working world

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 (across all HAS sectors)



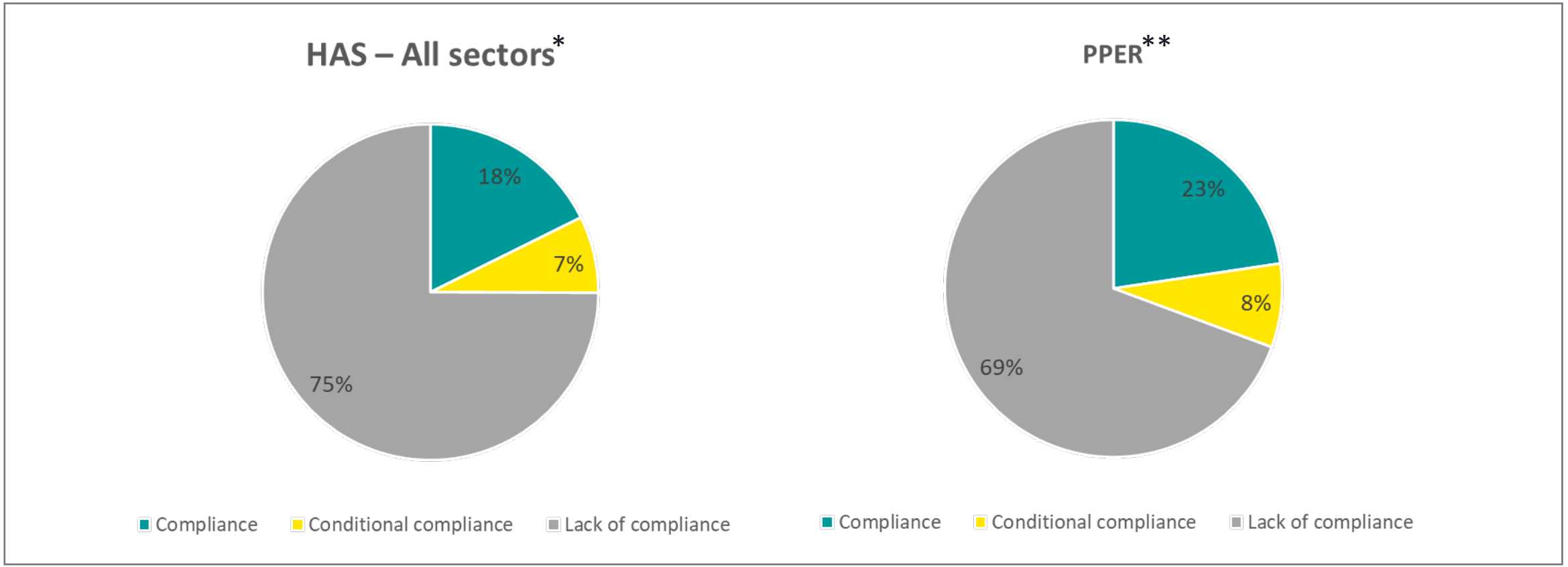
31

days is the **median** duration of completed ARs since May 2025.

34

days is the **average** duration of completed ARs since May 2025.

Assessment compliance outcomes

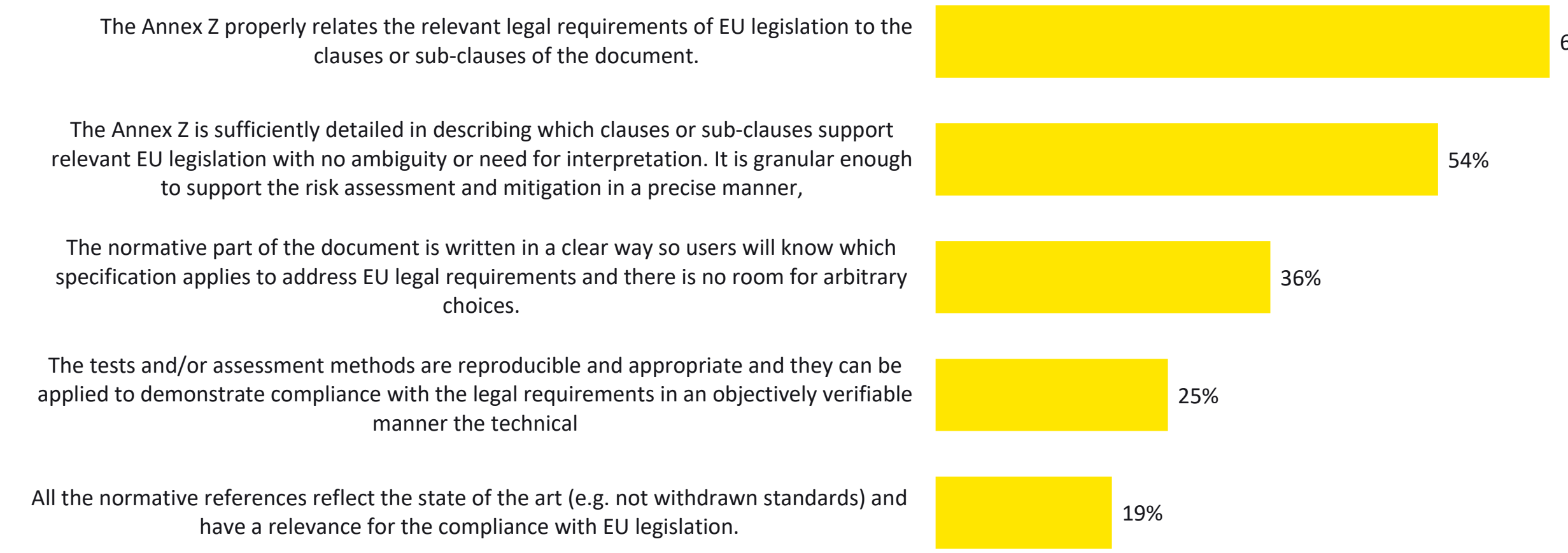


*n=2814 completed assessments

**n=137 completed assessments

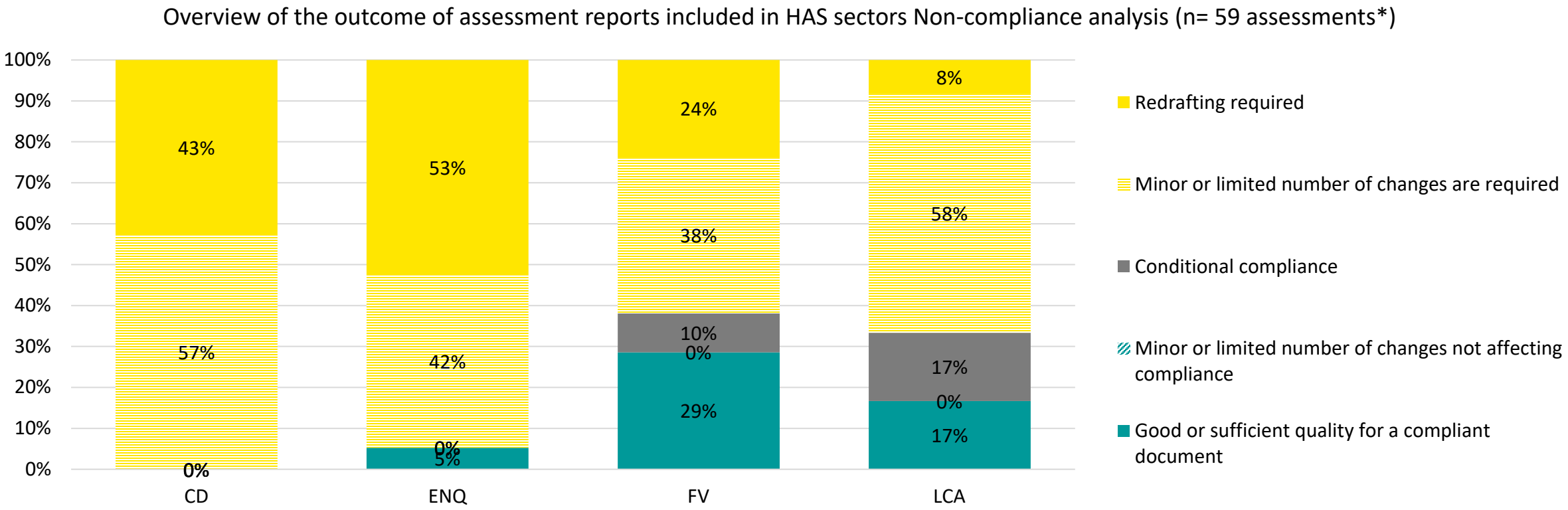
Top 5 findings leading to Lack of Compliance in PPER assessments

Requirements **not met***:



*Based on 59 assessments analysed since the introduction of the new report template

Share of AR outcomes by stage in PPER sector



*Based on 7 CD, 19 ENQ, 21 FV, and 12 LCA-stage assessments.

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 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

Drafting standards for compliance with European Legislation: Best Practices in PPER standards

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

Shape the future with confidence

Introduction and general rules

Aim of harmonised standards

Introduction and general rules

- A harmonised standard must be drafted to provide technical solutions to satisfy the Essential Requirements (ERs) of Regulation (EU) 2016/425 applicable to a given product.
- Conformity with a harmonised standard so set, the reference number of which is published in the OJEU, provides a **presumption of conformity with the applicable essential requirements of Regulation (EU) 2016/425**
- Presumption of conformity is only given within the limits of the scope

Technical solutions

- The technical solutions must provide:

  - ✓ **A concrete and mandatory requirement.**
  - ✓ **The full associated test method or way to verify the requirement, and**
  - ✓ **The pass/fail criteria**

- If any of them are missing or incomplete, the ER cannot be considered as satisfied

Best practices in drafting harmonised standards

Foreword

- The Foreword shall not contain requirements, legal or technical interpretations.
- The list of changes with respect to the previous standard shall be included in the Foreword.

Scope

- **The scope does not set requirements**
- The scope should give an indication of the products that are covered by the standard and those that are excluded.
- Pay attention to alignment between the **title of the standard and the scope**, and with Annex ZA
- **Note: The scope should never be cited in Annex ZA**.

Scope

- **Lack of indication of part of the body protected:**

✗ … providing protection of the wearer …

✓ … providing protection **to the full body** of the wearer …

- **Lack of indication of the risk against which the PPE protects:**

✗ … providing protection to the user …

✓ … providing protection **to the hands of the user against heat and fire** …

Normative references

- **The document shall contain only dated normative references.**

- The following normative references are accepted in clauses, subclauses or paragraphs that refer to the "harmonised part" of the standard:
  - ✓ European standards (ENs, or even to CENELEC HDs)
  - ✓ International standards (ISO, IEC, ISO/IEC, or ITU-T standards)
  - ✓ CIE standards (International Committee for light and lighting standards)

- References to **ISO or IEC** standards could be undated in the text of the standard in case of European adoption of international standards, provided that there is a **European Annex containing the specific year of the version** to be used in the context of the standard.

Normative references

- References to drafts can be accepted when drafts are developed in parallel (test methods or particular requirements) – conditional compliance.
- Please check the availability of referenced drafts of standards for HAS Consultants.
- Informative references in clauses that generate legal effect are **not acceptable**.

Normative References

- **EN standards**
  - ✗ EN 13087-1
  - ✓ EN 13087-1:2000
- **ISO standards**
  - ✗ ISO 9227 (without including a Table ZA.2)
  - ✓ ISO 9227 (including a Table ZA.2), or
  - ✓ ISO 9227 :2022
- **Other standards**
  - ✗ ASTM D6482-21

Requirements

- **The normative part of the document shall contain requirements that are coherent with EU legislation**
- Technical solution should define **clear, objective and repeatable test methods and requirements**
- No references to alternative test methods without selection criteria.
  - If alternative test methods are recommended, clear information concerning their selection is required.

- For example:
  - different risks require other testing methods (e.g. gas permeation – method A, liquids permeation – method B)
  - different material or design of machines requires alternative testing methods (e.g. Plastic perforation insert - method 1, metal perforation insert – method 2).

- Conditional choices are allowed as long as there is a **clear, objective and reproducible criterion** for each choice.

Reproducible and appropriate tests and/or assessment methods

- **Reproducible:**
  - Clear specification of testing device (apparatus), description of sampling and testing procedure (including uncertainty of measurement) and necessary information concerning e.g. pretreatment, ambient conditions, time.
- **Appropriate:**
  - Test method should simulate real conditions of use (intensity and duration of hazards).
- **Objectively verifiable:**
  - If possible, maximum (range) values, data necessary for estimation of uncertainty of measurement, clear pass/fail criteria (including uncertainty).

Good practice - uncertainty of measurement

Test methods and pretreatment conditions:

- **Description of tests methods** (pretreatment procedure) should include:
  - tolerances for values (e.g. dimensions, forces, temperatures, time, chemical purity of reagents),
  - data concerning measurement accuracy of apparatus.
- **Representativeness of tested samples**
  - Cleary specified number (size) of samples for tests (if appropriate, samples selection criteria).
- **Use of SI units is recommended**.
- **Requirements** – pass/fail
  - Measurement value + uncertainty of measurement should be below (in range) the values specified in standard.

See series „**Guides to the expression of uncertainty in measurement (GUM series)”,** particularly **JCGM 106** – „Evaluation of measurement data – The role of measurement uncertainty in conformity assessment (ISO/IEC Guide 98-4)”

The technological neutrality and performance-based principles

Requirements should focus on:

- **Products, not the role of manufactures or testing laboratories**
  Example: Routine tests are not harmonised part of the standard.

- **Safety parameters rather than specification of materials**

  Example: Mechanical properties despite minimum thickness of material.

The standard should contain technical solutions supporting Essential Requirements given in Annexes despite requirements stated in the main text of the Regulation.

Requirements

Non-specific requirements

✗ … materials shall be sufficiently strong

✓ Tensile strength shall be > 100 N

No test procedure

✗ The product shall be close fitting and able to be worn without discomfort or significant restriction to head movement and without reducing the field of view.

(No test procedure)

✓ The product shall be close fitting and able to be worn without discomfort or significant restriction to head movement and without reducing the field of view. Testing according to p.x of EN XXXX

Requirements

Unclear requirements

✗ Any garment and its component shall meet the relevant requirements of ISO 13688 in addition to the requirements set in this document.

(Unclear to which relevant requirements it refers)

✓ Any garment and its components shall meet the requirements in 4.2 and 4.3 of ISO 13688 in addition to the requirements set in this document.

Requirements

- **Neutrality principle**

✗ … test procedure which shall be provided by the manufacturer

✓ Test procedures must be defined by the own standard

✗ … samples selected as agreed between the interested parties

✓ Standard must define from where the samples must be selected

Requirements

- **Number of samples to be tested**

✗ Test tensile strength according to EN ISO 13934-1:2013
This standard refers to the number of samples to be tested as “at least” or “as a minimum”. This means that more samples may be tested. This could lead to different results. A concrete number of samples must be indicated.

✓ For tensile strength, three (3) samples in each direction (warp and weft) shall be tested according EN ISO 13394-1:2013

✗ At least three samples of each type of shield shall be supplied for testing

✓ Three samples of each type of shield shall be supplied for testing

Requirements

Cleaning

✗ Samples shall be washed three times before testing using:

a) Type B washing machine and parameters (normal cycle, warm temperature) in accordance with ISO 6330:2021, Table C.1

AATCC 1993 standard reference detergent 1 WOB, in accordance with ISO 6330:2021, Annex H.1

✓ Before testing, samples shall be cleaned according the manufacturer instructions

Regulation (EU) in its ER 1.4 gives manufacturer freedom to decide on the cleaning procedure. No specific procedure may be required.

Requirements

- **Results. Several samples tested**

✗ the result shall be expressed as the arithmetic mean (average) of the results from the individual test specimens.

Without the average qualified it could happen that the average meets the requirement, but some individual values fail. Not acceptable.

✓ The results shall be expressed as:

- the lower individual value,
- the higher individual value, or
- the average, provided that all the individual values met the requirement.

Standard does not unsuitably repeat legal requirements.

No copy and paste of ERs!

- Requirements should contain added value, preferably appropriate technical solution (including references to testing method, field testing, questionnaires).

Examples: Innocuousness and Ergonomic

ER 1.2.1.1. The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

ER 1.2.1.1. The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

ER 1.2.1.2 Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

Test methods. Uncompleted test procedures

Ergonomics

✗ To assess the requirements of 4.1, an observer shall monitor the test subject's experience and answer the following questions:

a) Was it possible to put on and remove the protector without difficulty?

b) Were you able to adjust the protector according to the manufacturer's instructions?

c) Can the following movements be carried out without difficulty and does the protector remain in place during each movement:

1) Vigorously moving (shaking) the protected body part while standing and during walking?

2) Bending at the waits, twisting, jumping in place, while wearing the protector?

3) Walking at moderate speed

✓ It lacks how many times the movements in 1), 2) and 3) have to be repeated, what is “moderate speed” and how long the subject must walk

Test methods - Uncompleted test procedures

Textiles - Tear properties of fabrics

X **Aparatus**

A CRE machine shall be used for testing

It lacks characteristics of the CRE machine, e.g. constant-rate-of-extension; gauge length to be set, accuracy of the apparatus (class).

Annex ZA - Clarity and Granularity

- Annex ZA should contain references to relevant points or subpoints despite general clauses.
- References to “whole standard” and informative parts of standards (Annexes) and Scope are not acceptable.
- References to testing methods are also not acceptable.
- Annex ZA should support risk assessment related to products.

- Remark: Please read carefully text of the ER despite title before giving references to points or clauses (e.g. ER 2.4 PPE subject to ageing)

Annex ZA

- Often, when deciding which ERs apply, only the ER heading is considered, forgetting that the ER content provides information about its applicability and how to satisfy it.
- Considering only the ER heading can lead to mistakes in its application and compliance. This can lead to clauses not related to the ER being used as a way to verify the ER.
- **The complete content of the ER must be considered**

Annex ZA

- In addition to reflecting the applicable ERs considered in the standard, Annex ZA must comply with what is required in the Standardisation Request M/571, mainly in its Annex II, Part A, 2.

X

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirements of Regulation (EU) 2016/425	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.2.1 Absence of inherent risks and other nuisance factors	4.1.1	
1.2.1.1. Suitable constituent materials	4.2; 4.3	
1.3.1. Adaptation of PPE to user morphology	4.4	
1.3.2. Lightness and strength	5	
1.4 Manufacturer's instructions andinformation	6	
2.4. PPE subject to ageing	6	
3.6. Protection against heat and fire.		
3.6.1. PPE constituent materials and other components	4.5.1	
3.6.2 Complete PPE ready for use	4.5.2	

- Requirement in Standardisation Request **not fulfilled**

Annex ZA

Table ZA. 1 according to Standardisation Request M/571, Annex II, Part A, 2:

✓ **Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425**

Essential Requirements ofRegulation (EU) 2016/425	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
1.1.1 Ergonomics		Not covered
1.1.2.1. Optimum level of protection.		Not covered
1.1.2.2. Classes of protection appropriate to different levels of risk.		Not applicable
1.2.1 Absence of inherent risks and other nuisance factors	4.1.1	
1.2.1.1. Suitable constituent materials	4.2; 4.3	
1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user		Not covered
1.2.1.3. Maximum permissible user impediment		Not covered
1.3.1. Adaptation of PPE to user morphology	4.4	
1.3.2. Lightness and strength	5	
1.3.3. Compatibility of different types of PPE intended for simultaneous use		Not applicable
1.3.4. Protective clothing containing removable protectors		Not applicable
1.4 Manufacturer's instructions andinformation	6	
2.4. PPE subject to ageing	6	

- Requirement in Standardisation Request **fulfilled**

Annex ZA

Use of standards in the column Remarks/Notes:

X

Table ZA.1 — Correspondence between this European Standard and Regulation (EU) 2016/425

Essential Requirementsof Regulation(EU)2016/425	Clause(s)/sub-clause(s)ofthis EN	Remarks/Notes
1.1.1 Ergonomics	4.1.1	ISO 13688:2013+Amd.1:2021
1.1.2.1 Optimum level of protection	4.1.1	ISO 13688:2013+Amd.1:2021
1.2.1 Absence of risks and other inherent nuisance factors	4.1.4, 4.2.5, 4.2.6, 7.1k)	
1.2.1.1 Suitable constituent materials	4.1.3.1	
1.2.1.2 Satisfactory surface condition	4.1.3.2	
1.2.1.3 Maximum permissible user impediment (sensory)	4.1.1	ISO 13688:2013+Amd.1:2021
1.3.1 Adaptation of PPE to user morphology	4.1.5, 4.1.6	

- References to other standards could indicate that the clause or sub-clause in question should be reconsidered or redrafted**. Annex ZA should simply describe the relationship between clauses of the document and the relevant legal requirements**

Q&A session

Your feedback

European Standardization Organizations

Thank you for your participation!

Upcoming events/webinars:

2026-01-22: CRA Standards Unlocked: Deep Dive Session on Cybersecurity Requirements for Hardware Devices with Security Boxes

2026-02-05 - Stakeholder Workshop 'Leveraging the Single Market and competitiveness – The role of European standards'

2026-03-12: 10th Cybersecurity Standardization Conference