

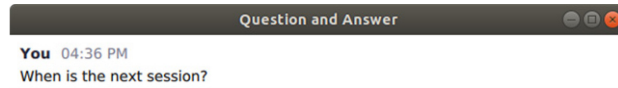
European Standardization Organizations

Drafting for compliance: best practices for standards in support of the Toy Safety Directive and General Product Safety Regulation'

*We start
at
10:00*

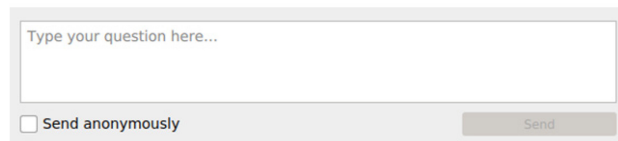
Get the most out of the webinar today

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



Question and Answer

You 04:36 PM
When is the next session?



Type your question here...

☐ Send anonymously Send

- ▶ Talk about us on LinkedIn, Bluesky and Instagram with #training4standards

Agenda

10:00	Welcome
10:05	Opening remarks by the European Commission
10:10	Key development processes and drafting reminders (CCMC)
10:25	HAS process overview & sector update (EY)
10:40	Best practices and recurring issues (HAS Consultants)
11:20	Q&A
12:00	End of the webinar

Opening remarks by the European Commission

Annalisa LA ROVERE (DG GROW – Desk Officer Toy safety Directive)

Marie GERARDY (DG JUST - Legal and Policy Officer)



Toy Safety Directive 2009/48/EC An introduction

**Training webinar for TCs
25 November 2025**

Toy safety team - Unit F2

European Commission

Directorate-General for Internal Market, Industry,
Entrepreneurship and SMEs

Directive 2009/48/EC ("Toy Safety Directive")

- Fully applicable in all 28 EU countries since July 2013
- Specific obligations for economic operators
 - ✓ Safety requirements + procedure to prove conformity
 - ✓ Documentation requirements
 - ✓ Labelling requirements
- Free circulation of compliant toys in all 28 EU countries

What is a toy?



Toys are products:

- ✓ designed or intended
- ✓ whether or not exclusively
- ✓ for use in play
- ✓ by children under 14 years of age

Toys are governed by the EU Toy Safety Directive 2009/48/EC.



A toy has to be safe (1)

The manufacturer placing a toy on the EU market has to ensure that it complies with:

1. General safety requirement (Art. 10.2 TSD):

Toys ... must not jeopardise the health and safety of the child playing, nor of others (parents, child carers, ...) when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

A toy has to be safe (2)

2. Particular safety requirements (Annex II TSD):

- ✓ Physical and mechanical properties (incl. small parts, sound)
- ✓ Flammability
- ✓ Chemical properties (incl. allergenic fragrances, 19 metallic 'elements')
- ✓ Electrical properties
- ✓ Hygiene (incl. microbiological safety)
- ✓ Radioactivity

Safety requirements are **not** the same as standards!
Standards are **not** mandatory in the EU!

Presumption of conformity (1)

Toy Safety Directive 2009/48/EC:

Article 13

Presumption of conformity

Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 and Annex II.

Presumption of conformity (2)

In short:

A toy that conforms

- with all those specifications in referenced harmonised standard(s)
- that apply to that particular toy

is presumed to conform to all the applicable requirements of the Toy Safety Directive 2009/48/EC.

Such a toy can be placed on the market in the EU.

Procedure to prove conformity: conformity assessment (1)

Two possible conformity assessment procedures:

1. Conformity assessment by the manufacturer himself ("self-certification")

If the manufacturer applies referenced harmonised standards, and all the relevant safety aspects of his toy are covered by those standards

- EN 71: for all properties other than electrical
- EN 62115: for electrical properties

 Manufacturer certifies the conformity himself!

Procedure to prove conformity: conformity assessment (2)

2. Conformity assessment by a Third Party ("EC-type examination")

- If the relevant safety aspects of the toy are not entirely covered by harmonised referenced standards
- If the manufacturer has applied the referenced harmonised standards only in part or not at all
- If the manufacturer considers that the toy needs to be assessed by a Third Party



Third Party (= 'Notified Body')

- carries out the conformity assessment
- certifies the conformity by issuing an **EC-type examination certificate**

Why are harmonised standards important?

- Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that toys comply with relevant EU legislation.
- Support facilitate the effective implementation of EU legislation and the functioning of the Single Market.
- ensuring the safety, interoperability, and competitiveness of products and services across Europe.

Current Toy Safety Standards (1)

- Provide specifications to find out whether a toy fulfils the safety requirements
- EN 71 consists of several parts
 - ✓ EN 71-1 Safety of toys — Part 1: Mechanical and physical properties
 - ✓ EN 71-2 Safety of toys — Part 2: Flammability
 - ✓ EN 71-3 Safety of toys — Part 3: Migration of certain elements
 - ✓ EN 71-4 Safety of toys — Part 4: Experimental sets for chemistry and related activities
 - ✓ EN 71-5 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets
 - ✓ EN 71-7 Safety of toys — Part 7: Finger paints — Requirements and test methods

Current Toy Safety Standards (2)

- ✓ EN 71-8 Safety of toys — Part 8: Activity toys for domestic use
- ✓ EN 71-12 Safety of toys — Part 12: N-Nitrosamines and N- nitrosatable substances
- ✓ EN 71-13 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games
- ✓ EN 71-14 Safety of toys — Part 14: Trampolines for domestic use
- EN 62115 Electric toys — Safety

All the 'harmonised' standards listed above in (1) and (2) have been referenced in:

- [Commission Implementing Decision \(EU\) 2023/740 of 4 April 2023 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council - OJ L 96, 5 April 2023](#)
- [Amendment of 9 September 2025 to Implementing Decision \(EU\) 2023/740](#)

Current standardisation request for toys M/589 (Commission Implementing Decision C(2022) 7410)

Adoption date		Status
24 October 2022		Under execution
ESOs notified		
CEN (accepted) , CENELEC (accepted)		
Intended purpose		
Harmonised standards supporting EU harmonisation legislation		
Related legislation		
2009/48/EC		
Policy area(s)		Subject(s)
Consumer protection		Toys
Expiration date		
25 October 2026		

ANNEX I

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

Table 1: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		Deadline for the adoption by the ESOs
1.	Flame retardants TCEP, TCPP, TDCP Elaboration of a new standard on 'TCEP and alternative flame retardants'	25 October 2025
2.	Bisphenol A Elaboration of a new standard on 'Bisphenol A'	25 October 2025
3.	Formamide Elaboration of a new standard on 'Formamide in foamed toy materials'	25 October 2026
4.	Isothiazolinones (CMI, MI and BIT) Elaboration of a new standard on 'Isothiazolinones'	25 October 2026
5.	Phenol Elaboration of a new standard on 'Phenol'	25 October 2026

Table 2: List of existing standards to be revised and deadlines for their adoption

Reference information		Deadline for the adoption by the ESOs
1.	EN 71-1 'Mechanical and physical properties'	25 October 2025
2.	EN 71-2 'Flammability'	25 October 2025
3.	EN 71-3 'Migration of certain elements'	25 October 2025
4.	EN 71-4 'Experimental sets for chemistry and related activities'	25 October 2025
5	EN 71-5 'Chemical toys (sets) other than experimental sets'	25 October 2025
6.	EN 71-7 'Finger paints – Requirements and test methods'	25 October 2025
7.	EN 71-8 'Activity toys for domestic use'	25 October 2025
8.	EN 71-13 'Olfactory board games, cosmetic kits and gustative games'	25 October 2025
9.	EN 71-14 'Trampolines for domestic use'	25 October 2025
10.	EN 62115 'Electric toys – Safety'	25 October 2025

Future standardisation request

*After the adoption of the new (forthcoming) Toy safety Regulation:
New mandate to be given to the ESOs to support the new requirements*

*See [Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC](#)
that will further improve children's protection, in particular from harmful chemicals*

More information

- EU toy safety homepage
http://ec.europa.eu/growth/sectors/toys/index_en.htm
- Text of the Toy Safety Directive
Amendments of the Toy Safety Directive
Other EU legislation relevant to the toy industry
Revision of Directive 2009/48/EC on the safety of toys
http://ec.europa.eu/growth/sectors/toys/safety/legislation_en

Harmonised standards for toys

[Toy safety - Internal Market, Industry, Entrepreneurship and SMEs](#)

Thanks for your attention!



For questions:
GROW-TOYS@ec.europa.eu

Key development processes and drafting reminders

Frédéric Mlanao, Account Manager at CEN and CENELEC

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

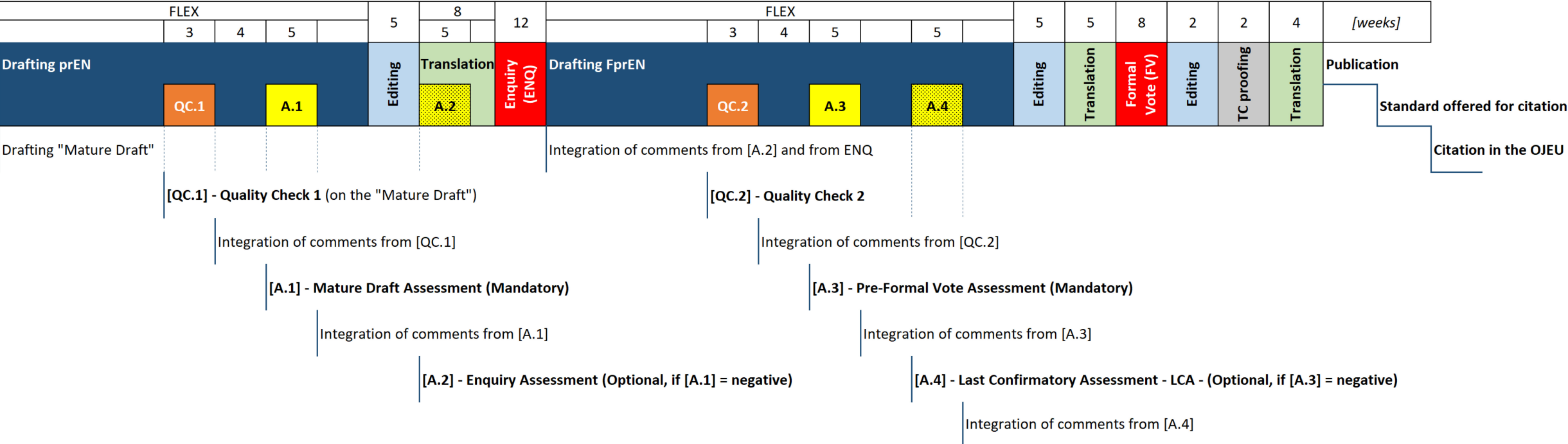
Innovative process based on 2 main pillars:

- ▶ 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



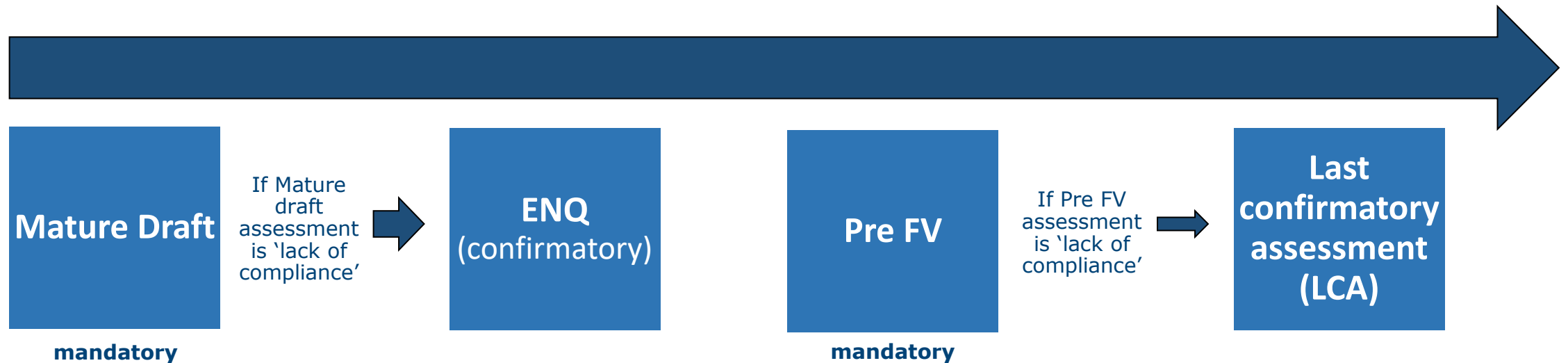
► Workflow



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

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

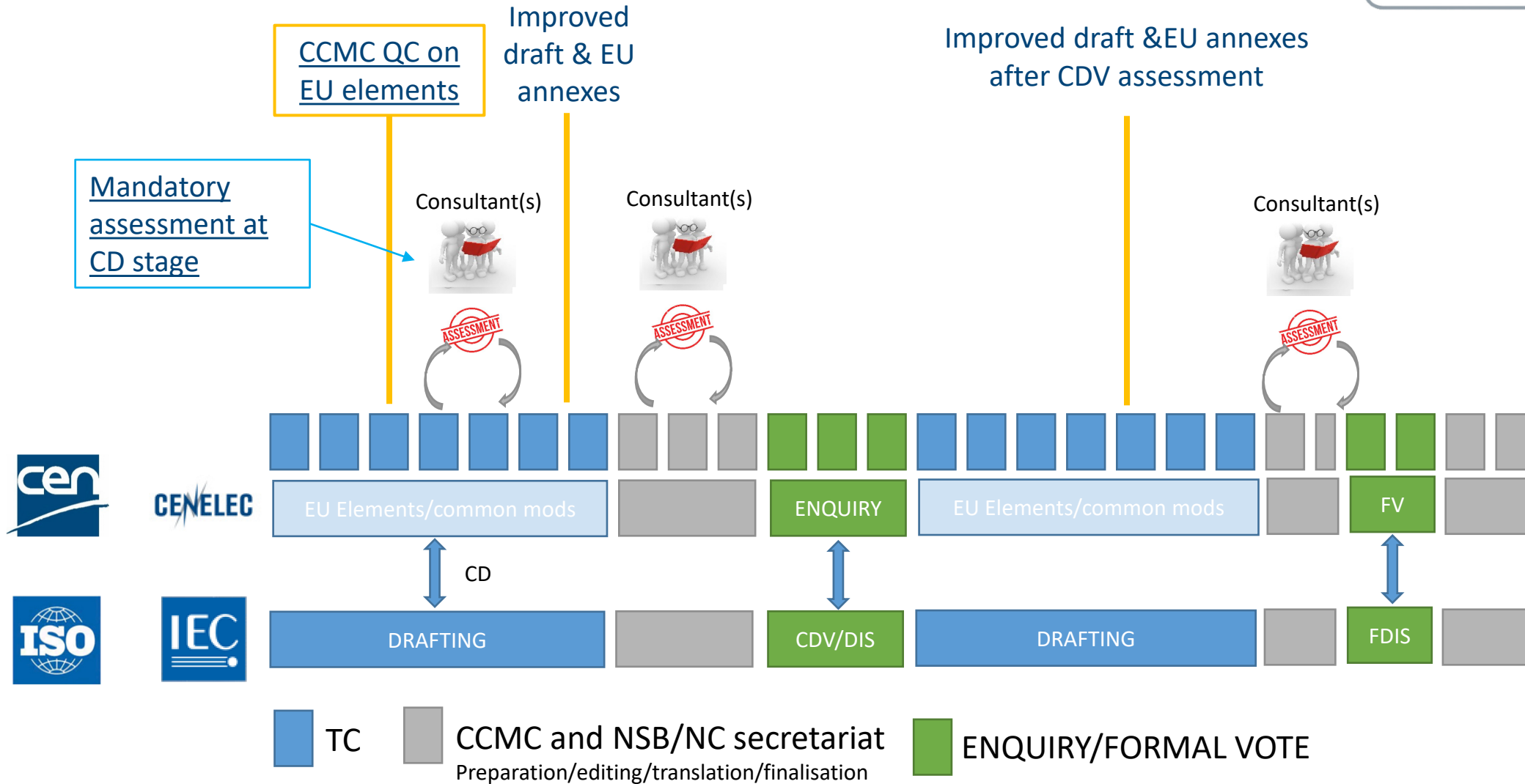
The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

'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 😊



- 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 \(hENs\)'](#)



European Committee for Standardization

General Product Safety Legislation

Clarity on the Annex ZA

Astrid Tomme

Sectoral Project Manager 'Energy and Living'

Glossary



- ▶ BT: Technical Board
- ▶ CCMC: CEN and CENELEC Management Center
- ▶ EN: European Standard
- ▶ ENQ: Enquiry
- ▶ FV: Formal Vote
- ▶ GPSR: General Product Safety Regulation (2023/988)
- ▶ GPSD: General Product Safety Directive (2001/95/EU)
- ▶ OJEU: Official Journal of the European Union
- ▶ SRAHG: Standardization Request Ad-Hoc Group
- ▶ TC: Technical Committee
- ▶ SReq: Standardization Request

Content



- ▶ Overview European Mandates under GPSR: specific cases
- ▶ How to tackle Annex ZA during GPSD – GPSR transitional period
 - ▶ Case 1. Red Mandates
 - ▶ Case 2. Purple Mandates
 - ▶ Case 3. Green Mandates

Overview

European Mandates under GPSR: specific cases



- ▶ M/253 Baby walking frames
- ▶ M/259 Consumer Safety of oil lamps
- ▶ M//264 Childcare articles
- ▶ M/266 Safety of consumers and children – lighters
- ▶ M/309 Draw strings on children's clothing

- ▶ M/372 Floating leisure products
- ▶ M/425 Fire Safety
- ▶ M/427 Cigarettes lighters
- ▶ M/452 Safety of music players
- ▶ M/464 Safety of child-care articles – drowning risks
- ▶ M/465 Safety of locking devices
- ▶ M/497 Childcare articles 'risks in the sleeping environment'
- ▶ M/505 Window blinds
- ▶ M/506 Stationary training equipment
- ▶ M/507 Gymnastic equipment
- ▶ M/508 Bicycles

- ▶ M/527 Children's seats
- ▶ M/531 Laser products
- ▶ M/538 Alcohol-powered flueless fireplaces

Case 1. Red mandates = invalid mandates

Pre-GPSD: 1 document including both safety requirements and standardization request

- **Not possible** to publish, offer and cite ENs for these old mandates in the OJEU that do not contain EC decision with Safety Requirements until new SReq for children's product is adopted
- Transitional solution to develop draft standards

Case 2. Purple mandates = mandates with conditions

Post GPSD but pre-Reg 1025/2012: safety requirements were adopted via a Commission Decision (Art.4 GPSD), but mandates not in proper format (1 single document)
→ Commission will renew them

- **Possible** to publish, offer and cite ENs for these mandates in the OJEU
- Condition 1: If fulfilling the **right** Safety Requirements Decision
- Condition 2: If justification of urgency is send to EC (before offering)

Case 3. Green mandates = valid mandates with condition

Post GPSD but pre-Reg. 1025/2012: safety requirement are adopted and mandates are in proper format

- **Possible** to publish, offer and cite ENs for these mandates in the OJEU
- Condition 1: If fulfilling the **right** Safety Requirements Decision

How to tackle Annex ZA during GPSD – GPSR transitional period

Case 1. red mandates

Case 1.



Annex ZA

Transitional solution for draft standards
until new SReq is adopted

M/253 Baby walking frames

M/259 Consumer safety oil lamps

M/264 childcare articles

M/266 safety of consumers and children - lighters

M/309 draw strings children's clothing

1. **Don't refer the old mandate in Annex ZA**

2. **Refer ONLY to NEW Decision on safety requirements
for children's products
= Commission Decision (EU) 2023/1338)**

HAS assessment can continue

Annex ZA (informative)

Relationship between this European Standard and the safety requirements of Regulation 2023/988/EU aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/XXX/C(202X) XXXX final¹ to provide one voluntary means of conforming to the safety requirements of Commission Decision (EU) No 2023/1338 of 28 June 2023 implementing General Product Safety Regulation 2023/988/EU of the European Parliament and of the Council with regard to safety requirements for children products and related products.

Once this standard is cited in the Official Journal of the European Union under that **Regulation 2023/988/EU**, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding safety requirements of that Regulation and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Commission Decision (EU) No 2023/1338 of 28 June 2023 implementing Regulation 2023/988/EU of the European Parliament and of the Council with regard to safety requirements for children products and related products and Commission's standardization request (Full reference to the request M/XXX)

Safety Requirements of EC Decision (EU) No 2023/1338 of 28 June 2023	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Product and product definition	Clause X	XXXX

IMPORTANT



“Shall my draft standard subject to
invalid red mandates be linked to legislation?”

YES if:

Draft standards **until FV:**

- Developed WITH Annex ZA
- To be assessed by HAS consultants

NO if:

Draft standards **to be submitted to FV:**

- TEMPORARY REMOVAL of the link to legislation
- Until new Sreq is adopted
 - Step 1. TC Decision to ask the removal of the link
 - Step 2. BT Decision on removal
 - Step 3. CCMC removes the link in the foreword and Annex ZA before FV
- No assessments at FV stage
- Once new SReq is adopted, link to GPSR achieved via amendments
→ fast track procedure (add Annex ZA: HAS + BT approval)

How to tackle Annex ZA during GPSD – GPSR transitional period

Case 2. Purple Mandates

Annex ZA

M/372 Floating leisure products

M/425 Fire safety

M/427 Cigarette lighters

M/452 Safety of music players

M/464 Safety of childcare articles – drowning risks

M/465 Safety of locking devices

M/497 Childcare articles ‘risks in the sleeping environment’

M/505 Window blinds

M/506 Stationary training equipment

M/507 Gymnastic equipment

M/508 Bicycles

1. Refer to the mandate

2. Refer to **the ‘old’ Decision on Safety Requirements**

→ **No need** to refer to the NEW Decision on safety requirement for children’s products
= Commission Decision (EU) 2023/1338)

EXAMPLE M/506

Annex ZA template for draft standards including 'old' decision on safety requirements

Annex ZA (informative)

Relationship between this European Standard and the safety requirements of Regulation 2023/988/EU aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/506/C(202X) XXXX final¹ to provide one voluntary means of conforming to the safety requirements of Commission Decision (EU) No 2011/476 of 27 July 2011 implementing General Product Safety Regulation 2023/988/EU of the European Parliament and of the Council with regard to safety requirements for stationary training equipment.

Once this standard is cited in the Official Journal of the European Union under that **Regulation 2023/988/EU**, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding safety requirements of that Regulation and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Commission Decision (EU) No 2011/476 of 27 July 2011 implementing Regulation 2023/988/EU of the European Parliament and of the Council with regard to safety requirements for stationary training equipment and Commission's standardization request (Full reference to the request M/506)

Safety Requirements of EC Decision (EU) No 2011/476 of 27 July 2011	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Product and product definition	Clause X	XXXX
A. General Safety Requirements	Clause Y. YY	YYYY

How to tackle Annex ZA during GPSD – GPSR transitional period

Case 3. Green Mandates

Annex ZA

M/527 Children's seats

M/531 Laser Products

M/538 Alcohol powered flueless fireplaces

1. Refer to the mandate

2. Refer to **the 'old'** Decision on Safety Requirements

→ **No need** to refer to the NEW Decision on Safety Requirement for children's products
= Commission Decision (EU) 2023/1338)

EXAMPLE M/538

Annex ZA template for draft standards including 'old' decision on safety requirements

FprEN 16647-1:2025 (E)

Annex ZA (informative)

Relationship between this European Standard and the safety requirements of Regulation 2023/988/EC aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/538 to provide one voluntary means of conforming to the safety requirements of Commission Decision (EU) No 2015/547 of 1 April 2015 implementing General Product Safety Regulation 2023/988/EC of the European Parliament and of the Council with regard to safety requirements for alcohol-powered flueless fireplaces.

Once this standard is cited in the Official Journal of the European Union under that **Regulation 2023/988/EC**, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding safety requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Commission Decision (EU) No 2015/547 of 1. April 2015 implementing Regulation 2023/988/EC of the European Parliament and of the Council with regard to safety requirements for alcohol-powered flueless fireplaces and Commission's standardization request 'M/538'

Safety Requirements of EC Decision (EU) No 2015/547	Clause(s)/subclause(s) of this EN 16647-1	Remarks/Notes
Product and product definition	Clause 1; Clause 3	
1.1. Construction and design requirements		
General requirements	Clause 1,	

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

An aerial photograph of a large group of triathletes in black wetsuits and white swim caps swimming in turquoise water. A single kayaker in a yellow shirt and white cap is in a red kayak in the center. A large yellow trapezoidal shape is on the left side of the image.

Roles and responsibilities,
processes and key tasks

HAS Support Team



**Joke
Wiercx**

Project
Manager



**Daan
Bijwaard**

Core Team
Leader



**Emilia
Pauwels**

HAS Operations
Coordinator



**Milko
Goossens**

Operational
Support



Julia Migda

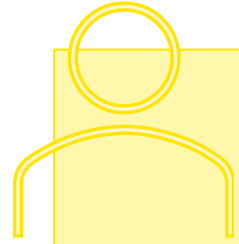
HAS Operations
Executor



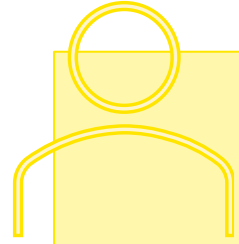
**Hanna
Falkiewicz**

Invoicing
Coordinator

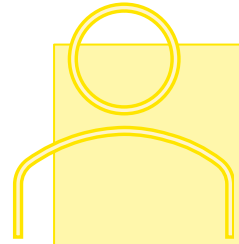
HAS Consultants (Toys and GPSR)



Alexander Rankin (Toys and GPSR)

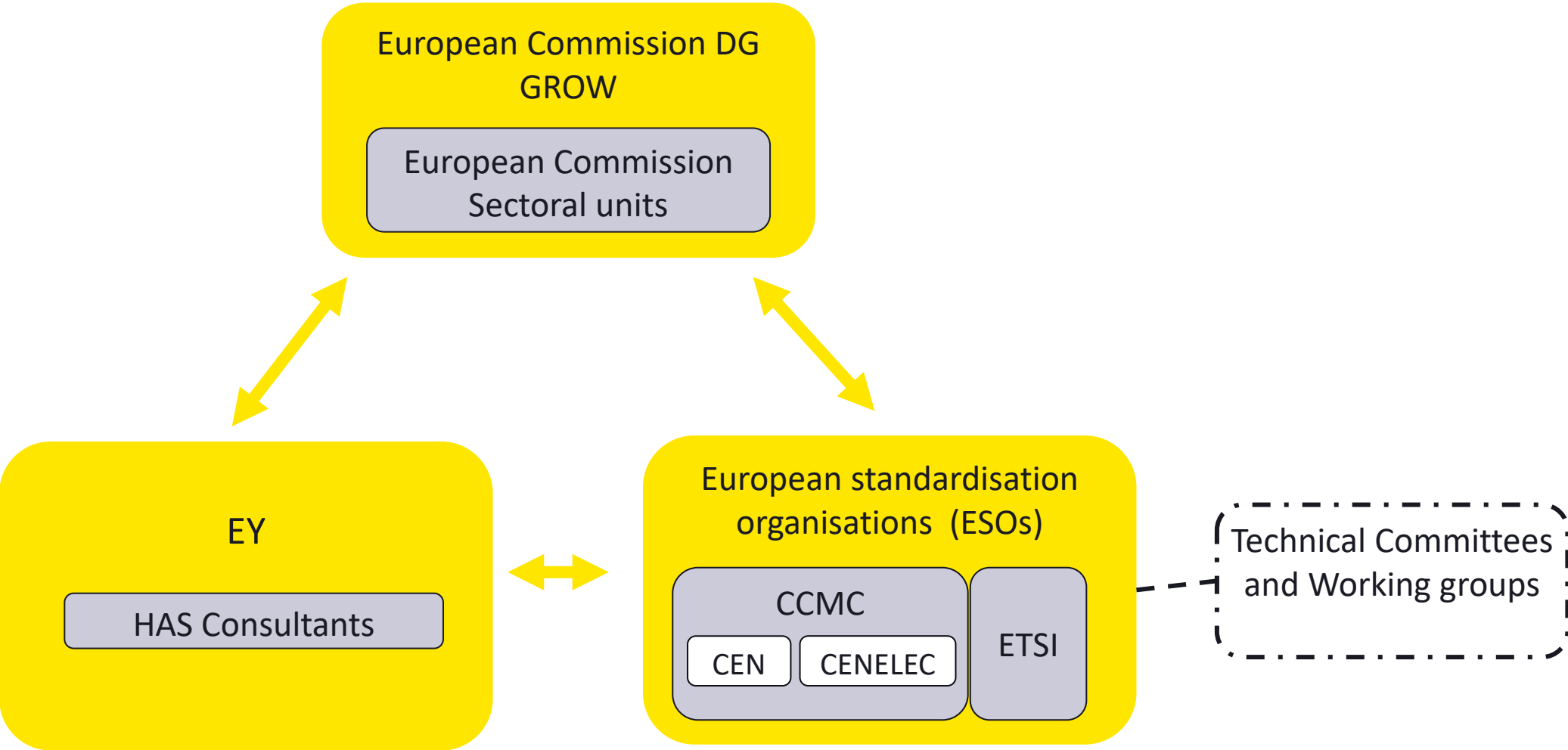


Giancarlo Bedotti (GPSR)

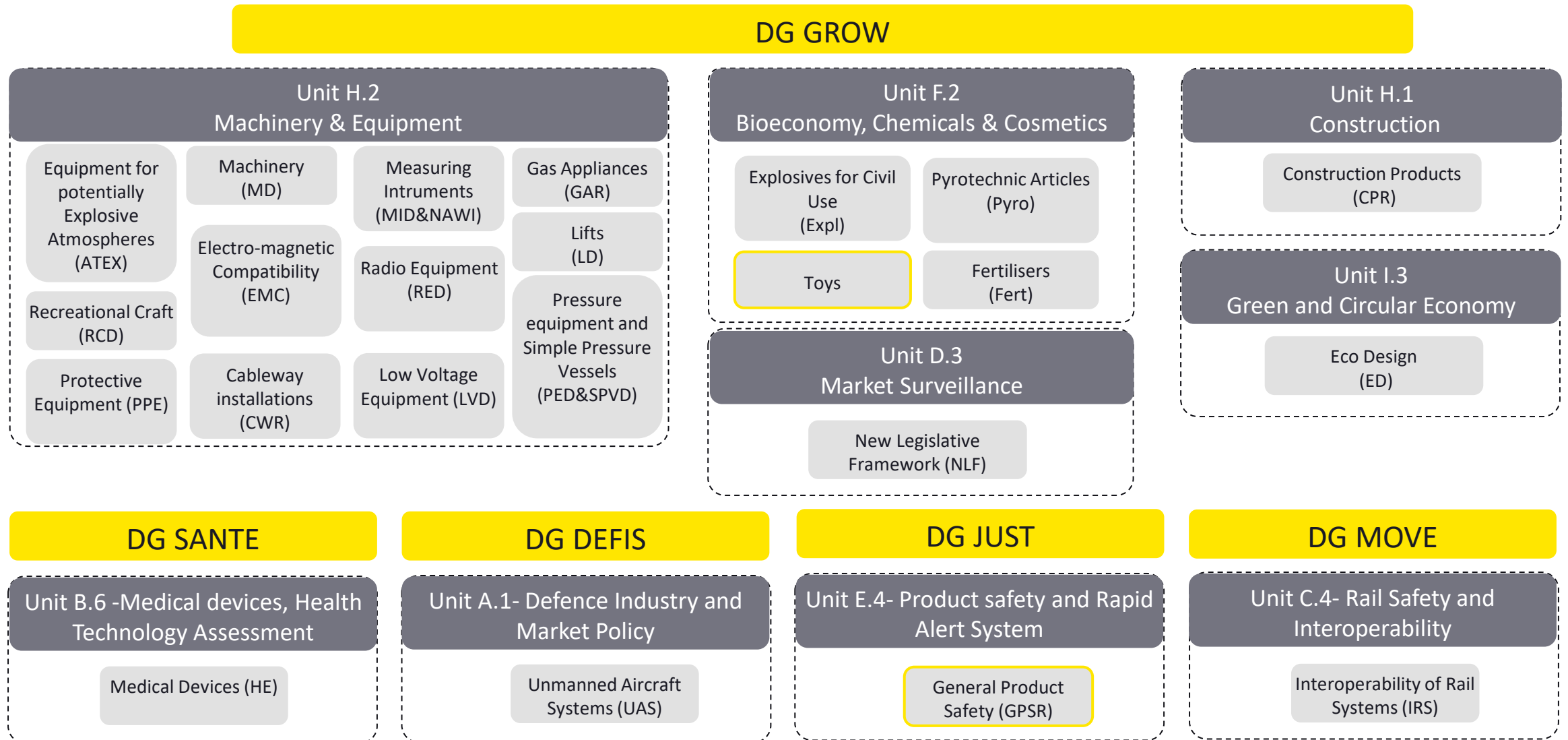


Mirosław Krzystolik (GPSR)

Key stakeholders



DGs involved and sectors covered



The HAS project as a Service

Service to the:

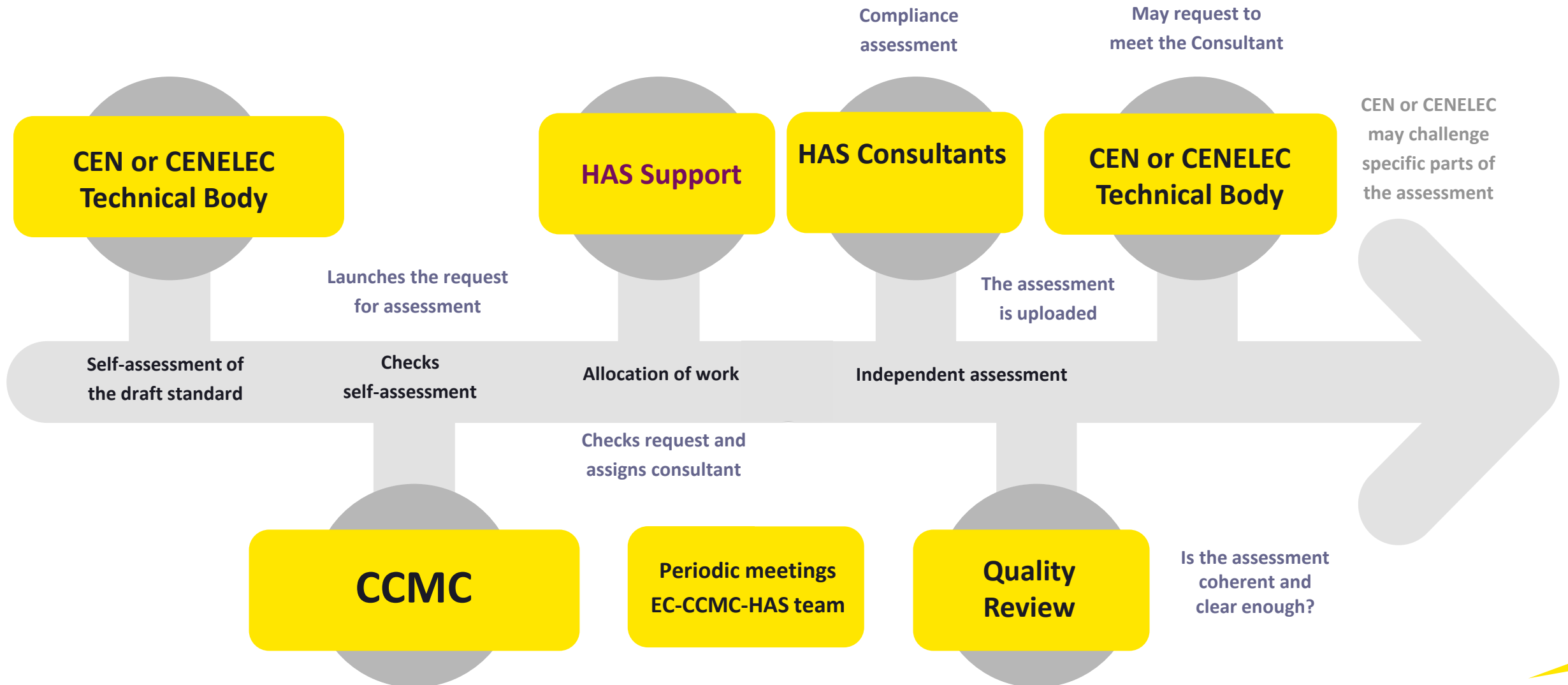
- ▶ European Commission
- ▶ Technical bodies of the European Standardisation Organisations

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

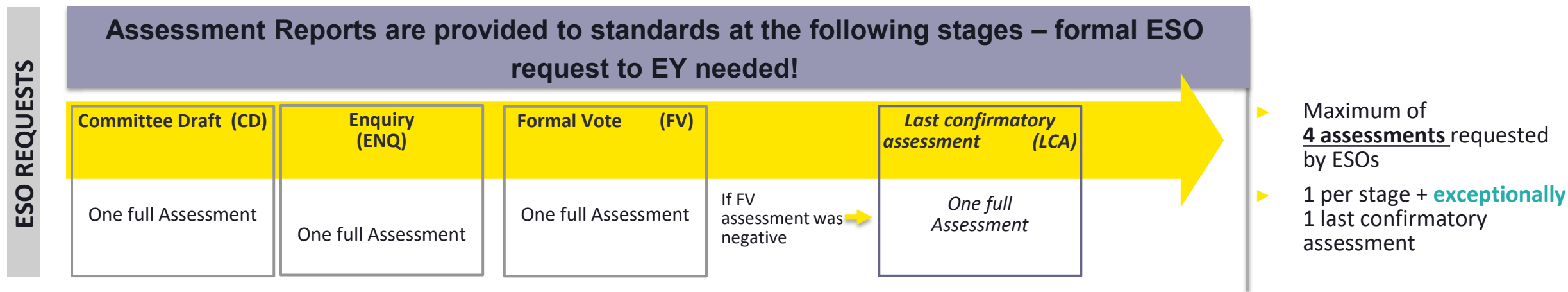
Main features:

- ▶ 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:

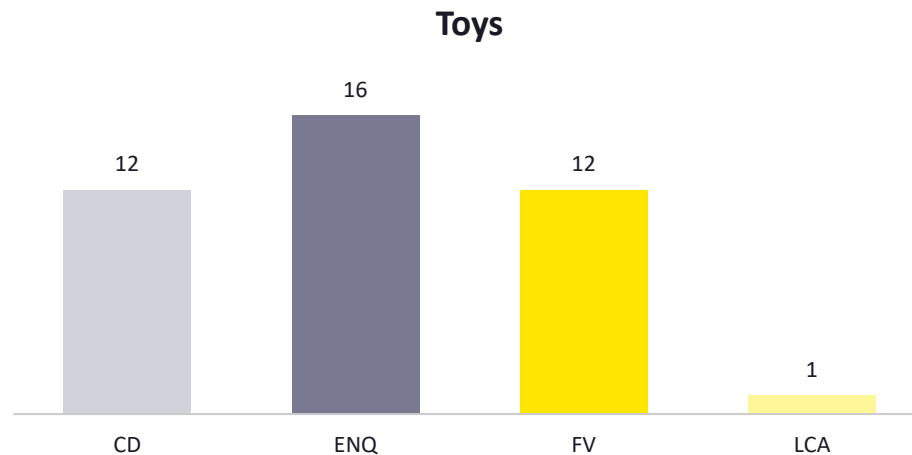
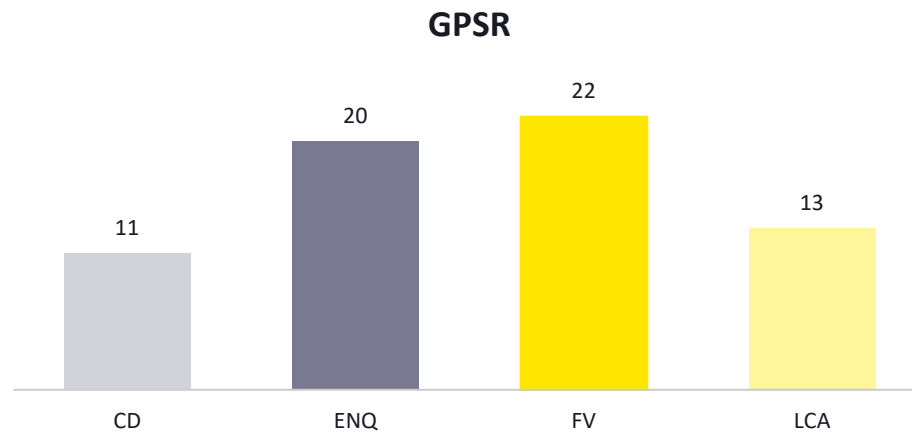
- ▶ Perform verification and assessment tasks
- ▶ Work in support of but do not represent the Commission
- ▶ Convey the Commission's positions to the ESOs or their technical bodies
- ▶ Are not allowed to modify their report(s) or assess revised documents during meetings with TCs
- ▶ Do not contribute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

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

An aerial photograph of a large group of triathletes in black wetsuits and white swim caps swimming in turquoise water. A single kayaker in a yellow shirt and white cap is in a red kayak in the center. A large yellow trapezoidal shape is on the left side of the image, containing the text.

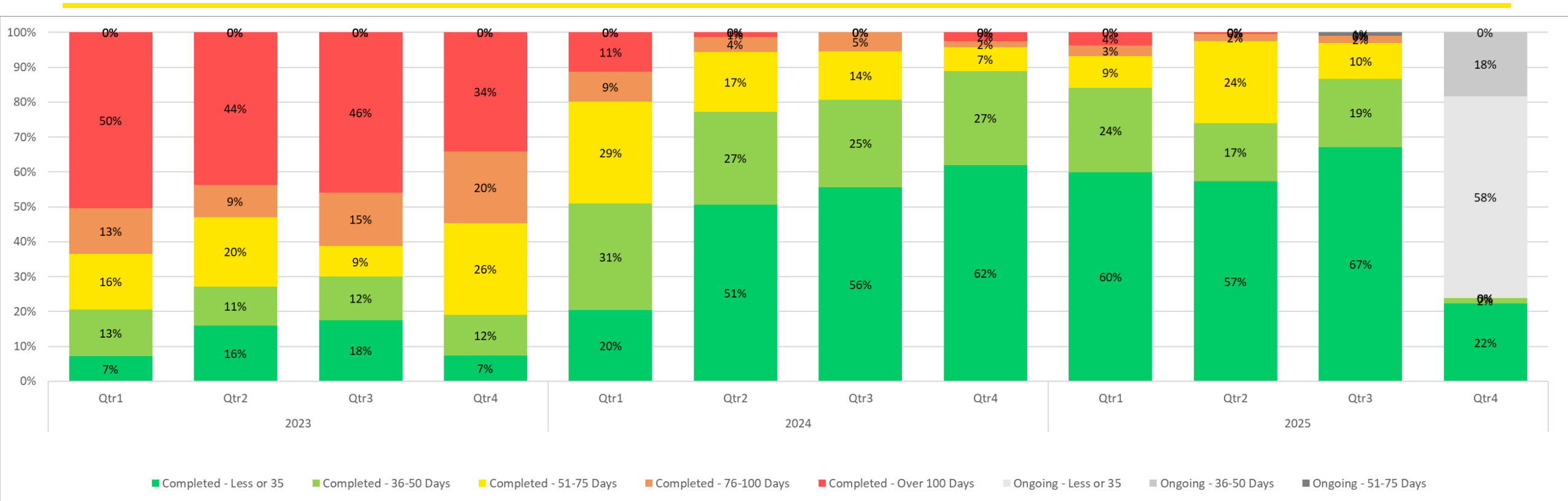
Update on the progress in
the assessment work

Stages of assessment requests



- ▶ TCs are **encouraged** to request 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)



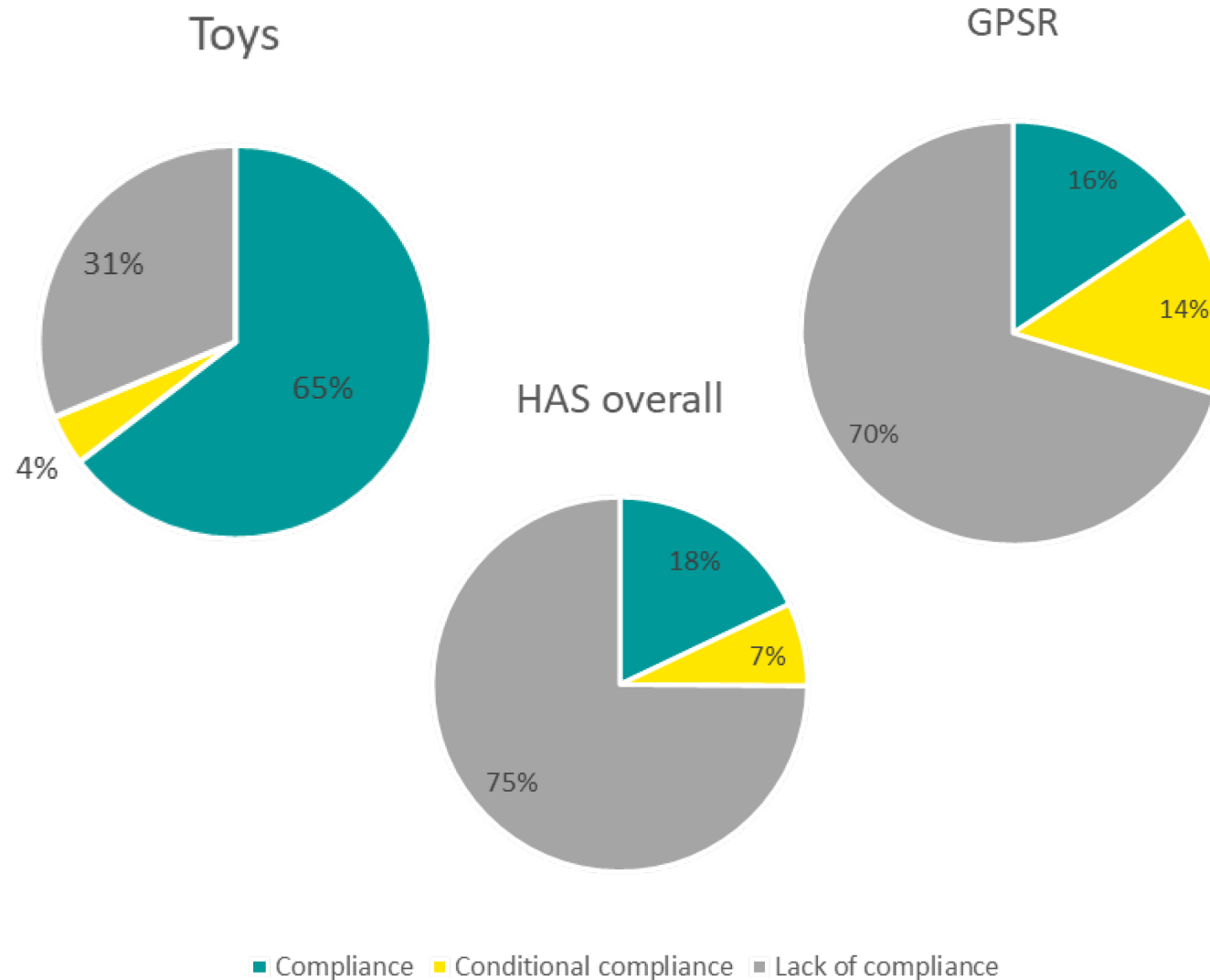
31

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

34

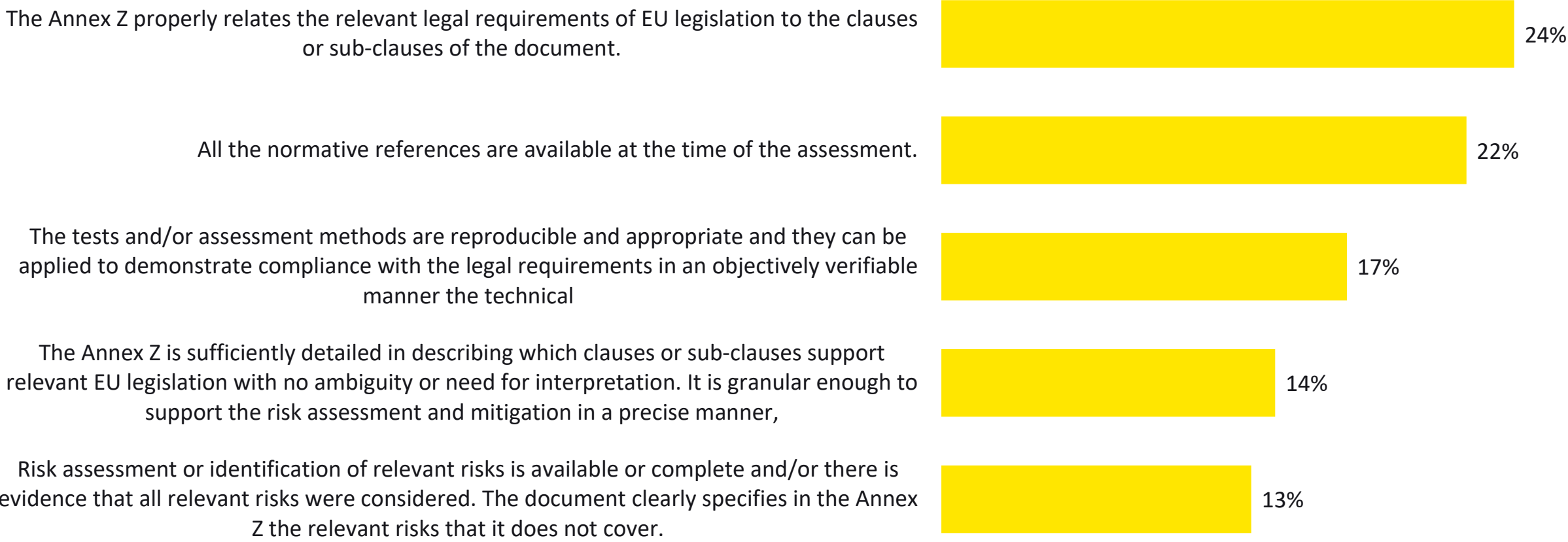
days is the **average** duration of completed ARs since May 2025.

Assessment compliance outcomes*

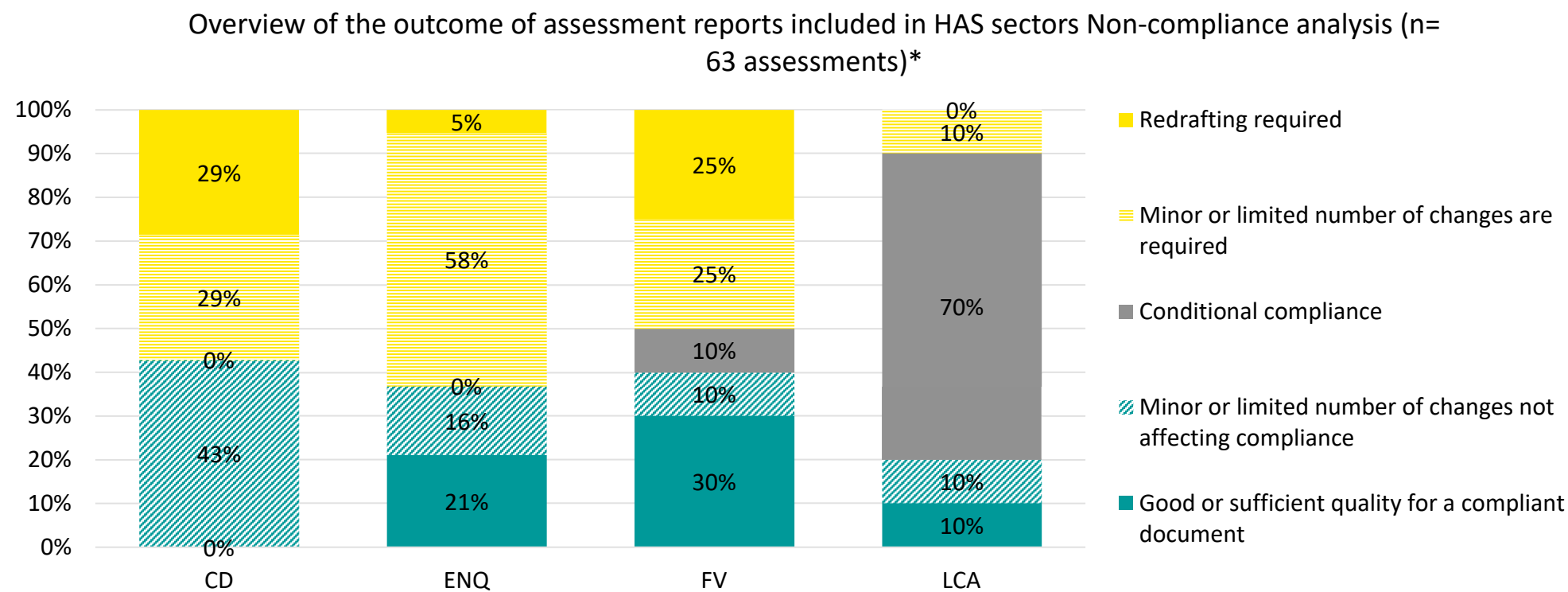


Top 5 findings leading to Lack of Compliance in Toys and GPSR sectors

Requirements not met:



Share of outcomes by stage of assessment requests in Toys and GPSR sectors



*Based on 33 Toys and 30 GPSR assessments completed since October 2023 (using new assessment template)

**Data for LCA stage is only reflecting GPSR assessments. No Toys assessments at LCA stage were included in this analysis.



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 for
drafting for compliance

-

Common mistakes &
how to avoid them.



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



Shape the future
with confidence

Introduction

- Alexander Rankin
- HAS Consultant & Regulatory Market Surveillance Consultant



Scope & definitions 1

- Please do not avoid certain harder product issues such as novel products by excluding them from the scope and/or definitions. In this way there is at least some control on undesirable or newly developed product types.
- Control of products of concern should be via performance requirements and not by exclusion in the scope or definition. You are the experts with regard to the State of the Art on the appropriate levels of safety and performance testing.
- Similarly, do not include any requirements (normally prohibitive) in the definitions of a product in order to simplify the drafting.

Scope & definitions 2

- Define the scope of the Harmonised Standard by the product and product types themselves and not by the activities of the TC. To do otherwise will not provide legal certainty.
- Although IR3 is silent on this matter apart from, *'14.1 Purpose or rationale. 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'*.
- To define by the jurisdiction of a TC links the scope to the unrelated organisational structure of a European Standards Organisation (ESO) and not to the EU present or future legislative definitions and product scope.

Unsuitable reproduction of legal requirements: 1

- Please do not copy and paste legal requirements without 'added value'. There are some specific legal requirements that should be highlighted:
- Chemical limits in the form of migration, volatile emissions, specific content levels etc. Here the specific legislative requirements take precedent. Standard only provides a preferred method of testing.
- Since 13.12.2024 there are specific GPSR EU 2023 988 legal requirements prescribing certain safety related information to be provided to the prospective consumer at the point of sale. Reproduction may well lead to confusion or misunderstanding of the legal requirements which are prescribed in the GPSR 2023 988
- Commission Notice C(2025) 7699 19.11.2025, 'Guidelines on the application of the EU general product safety legislative framework by businesses'.

Unsuitable reproduction of legal requirements: 2

- In relation to distance sales (including online sales) - certain product safety information and warnings should be clearly indicated to the prospective purchaser.

‘This product is intended for children able to sit up unaided and up to 3 years or a maximum weight of 15kg’
High Chairs EN 14988.

‘Do not use this product once your child can sit up unaided or weighs more than 9 kg’
Infant Swings EN 16232.

- We rely on the TC experts to determine what exactly should be indicated at point of sales, for example age or weight suitability, special safety conditions suitable for its safe use, etc.

Ensure all relevant risks are considered: 1

1. We rely on the TC expert participants to identify all relevant risks related to the toy or consumer products.
2. For consumer products, risks to the carer or adult user should also be identified and managed. For example, mechanical scissoring hazards associated with folding products may impact on both the child and carer.
3. All relevant risks should be based on the lifetime use of the product. In particular, endurance testing and premature ageing should be considered for specific high risk mechanisms and parts.

Ensure all relevant risks are considered: 2

1. All relevant risks should be with reference to foreseeable use of the product – including foreseeable misuse.
2. There should be evidence that all relevant risks were considered. (Assessment Report point 1.2.20)
3. The Annex Z should clearly specify the relevant risks that it does not cover. (Assessment Report point 1.2.20)

Test requirements: Good practice 1

Indicate clearly the order of testing. Certain tests will impact on the results of other test requirements.

But always remember that we are concerned with the safety of the product during its estimated lifetime.

Consider appropriate pre-test conditioning of the product to replicate 'real world' use of the product during its lifetime uses. Such as:

- Ageing due to external factors UV exposure, saliva or sweat etc
- Mechanical wear and tear
- Cleaning damage. Shrinkage or destruction of safety warnings on product
- Corrosion damage.

Test requirements: Good practice 2

- Where possible, require a single sample to comply with all requirements. This is to assist MSAs in their surveillance of the market, to align with the concept that these standards are safety standards - not quality assurance standards and to recognise the effect of the 'real world' where a product is subject to different effects during its lifetime.
- However, it is understood that more than one sample may be required where the assessment is that one test may unfairly affect the compliance with another later test. For example, a mechanical test may corrupt the results of a chemical test requirement.
- Maintain objectivity in the test requirements. Consider whether it is possible that 2 different competent users may reach different decisions.
- Be clear and consistent on which parts of the product shall meet the test requirements. Is it just parts accessible to the child / vulnerable user? How is this accessibility to be determined? Is it consistent?

Table ZA1

- The link between specific legislative requirements and how the Harmonised Standard addresses those requirements.
- The Annex ZA (Table ZA.1) must be sufficiently detailed in describing this link, with no ambiguity or need for interpretation.
- *The Annex ZA (Table A.1) must be granular enough to support the risk assessment and risk mitigation in a precise manner.*

Table ZA1: Continued 2

Clearly indicate the part of the legal requirement referred to in Column 1. For example, ‘Not the short-hand, ‘III.II.3’ **incorrect** but describe fully & clearly which article or which annex or which appendix. Examples:

- ‘Article XX. X’ **correct** or
- ‘Part XXX of Annex XXX’ **correct** or
- Point 2 of Part III of Annex II **correct**. For example e.g.:

Table ZA.1 — Correspondence between this European Standard and Directive 2009/48/EC

Essential Requirements of Directive2009/48/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
Annex II, III.1	Clause 4	
Annex II, III.3	Clause 4	
Art. 11.2	Clause 5	

Table ZA.1 Continued 3

Similarly Column 2 of Table ZA.1 should describe with as much granularity as possible the clauses or sub-clauses that support legislation.

The clause(s) to be inserted in Column 2 should be the requirements found in the Harmonised Standard at the finest level. So-called ‘granularity’.

Table ZA.1 — Correspondence between this European Standard and Directive 2009/48/EC

Essential Requirements of Directive 2009/48/EC	Clause(s)/subclause(s) of this EN	Remarks/Notes
Article 10, 2 (General)	Clause 5; Clause 6	
Article 11 (General)	Clause 6	
Annex II, I, 1 (Particular)	5.1; 5.2; 5.8, 5.10	
Annex II, I, 2 (Particular)	5.5; 5.7	
Annex II, I, 3 (Particular)	5.4	
Annex II, I, 11 (Particular)	Clause 4; 5.1; 5.3; 5.6; 5.7; 5.9, 5.11	

Table ZA.1 Continued 4

Do not include test methods in Table ZA.1 unless **specifically mentioned** in the legislation. I am not aware of any such requirements so far.

An example:

- Clause 8. Which includes both the requirements and the test method. **Incorrect.** Non-granular
- Clause 8.1.1. Which contains only the requirement,
‘ Shall meet the test requirements of Clause 8.2’. **Correct.** Granular.

Table ZA.1: Continued 5

Ensure the correct definition and the correct part of the Implementing Decision / Standardisation Request is used in the Harmonised Standard with regard to the normative requirements, the supporting Annex rationales and with regard to column 1 of the Annex ZA.1. This will assist legal certainty.

Decision EU 2023 1338 Safety Requirements to be met by European Standards for Certain Children's Products

2. THERMAL HAZARDS

Children's products shall be designed and manufactured in such a way that thermal hazards are limited as much as possible. The behaviour of the child and available data on the surface temperatures related to the burns shall be taken into consideration. Any residual hazards shall be covered by suitable warnings. Thermal hazards include, but are not limited to:

- (a) Contact with hot or cold surfaces.
- (b) Ingestion of hot foods or liquids.
- (c) Scalding.
- (d) Overheating (hyperthermia).
- (e) Becoming cold (hypothermia).

Table ZA.1: Continued 6

Several submitted Harmonised Standards have associated 'Thermal hazards' with 'flammability hazards', which are a completely separate form of hazard identified in the Decision.

Incorrect:

7 Thermal hazards

7.1 Requirements

When the sample is tested in accordance with 7.2, there shall be no surface flash and the rate of spread of flame shall not exceed 50 mm/s.

A separate sample may be used for these tests.

The rationales for these requirements are given in A.3.

A.3 Thermal hazards (see Clause 7)

If a product should come close to, or be in contact with, an ignition source the carer should be able to remove the child before injury occurs. If there is a possibility that the product will come into contact with a source of ignition any rate of spread of flame should be extremely slow.

Flash effect where the flame spreads across the surface of the material without the substrate burning should be avoided.

Be consistent with annex rationales 1.

The informative rationales contained in the annex are an explanation of the normative requirements contained in the text.

They provide a background to the normative requirements and indicate the current practical State of the Art with regard to requirements and tests. They indicate the 'real world' practicalities and problems of setting such normative requirements

We rely on the expertise of the participating committee members to determine the agreed normative requirements but it is helpful for a competent reader of the document to understand the development and purpose of the requirement

Be consistent with annex rationales 2.

Please make sure that all relevant normative provisions in the main text are clearly explained and not just certain provisions.

If there are problems in finding a State of the Art solution – then this should be explained. Indicate clearly what is perceived as possible and what is not.

Review informative rationale text for clarity so that a competent reader can clearly understand the background – often TC contributing experts are fully aware of the problems and issues but these should be explained to a new reader of the document. The user may be a test house, economic operator or market surveillance authority

Informative notes and bibliography

Excluded from assessment but perhaps good practice.

Consider informative notes and internally referenced informative bibliography listings on relevant legislative requirements, codes of practice, relevant research etc. In this way the competent user will be put on notice that there may be other requirements that should be further researched in relation to the pre-market conformity assessment of the product.

Whilst it is understood legislation takes precedent, that informative references to legislative requirements may date over time and that it is not the main task of TCs to signpost to legislation. The inclusion of informative references assists in presenting the whole picture.

A particular example are horizontal safety requirements for consumer products and toys such as REACH EC 1907 2006 Annex XVII restrictions on chemical safety.

Q&A session

Your feedback



Question time

- ▶ Use the Q&A panel to submit your questions

Question and Answer

You 04:36 PM

When is the next session?

Type your question here...

☐ Send anonymously

Send

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Frédéric Mlanao