



Workshop on the revision of Reg. 1025/2012 for the Sherpa sub-group of the High-Level Forum on European standardisation

Monday, 13 October 2025, 14:30 – 17:30

Agenda

14:30 – 14:40

Welcome and opening of the meeting by the Chair

14:40 – 15:00

**Introduction:
the Standardisation Regulation's revision process**

- Better Regulation framework by the Commission
- Impact assessment study by the Contractor

15:00 – 15:45

**Intervention logic and problem definition:
what do we need to improve?**

- Presentation by the Contractor
- Open discussion with the Members

15:45 – 15:55

Coffee break

15:55 – 17:00

**Policy options:
how can we improve the Standardisation Regulation?**

- Introduction by the Commission
- Open discussion with the Members

17:00 – 17:20

Data needs to support the impact assessment

- Data needs and possible contribution by the Members

17:20 – 17:30

Concluding remarks and end of the meeting by the Chair

Supporting EU competitiveness with a future-proof product framework The European Product Act

Context: Political commitments

EU Single Market Strategy, 21 May 2025

- ✓ “The Commission will seek to [...] enhance **the speed and flexibility** of the standardisation process, ensure a stakeholder-driven process with **balanced stakeholder participation** [...], improve **access to standards** and reinforce the EU's role as the **global standard-setter**.”
- ✓ “The NLF currently does not outline **the responsibilities of economic operators** involved in product circularity. [...]the EU product legislation needs to fully embrace **digital solutions**. The current reliance on traditional paper-based documentation is outdated”
- ✓ “There is a need for **EU-level governance of market surveillance**, to provide systematic coordination and guidance, scale up and pool the capacity and expertise of all market surveillance authorities across the EU”.
- ✓ “The EU product legislation framework is a major asset of the SingleMarket [...] based on (i) New Legislative Framework; NLF), (ii) a system of standards, and (iii) a market surveillance system. **It needs improvement**.”

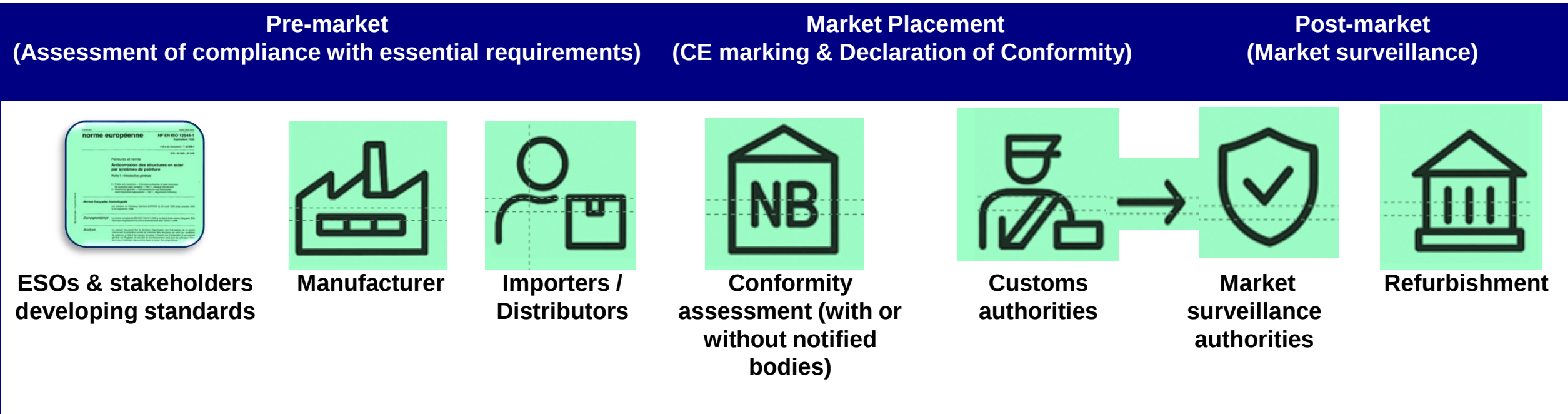
Review the **Standardisation Regulation**

Modernise **product legislation framework** to harness digitalisation, promote circularity and strengthen safeguards

Tapping into **synergies with capacities of the EU and national customs and market surveillance authorities** and potentially establishing an EU Market Surveillance Authority”

European Product Act approach –
consistent review of all 3 pillars

Rationale for a European Product Act: consistency across the full regulatory lifecycle



- **Regulatory consistency across the product lifecycle** from *design* to *compliance* (including software updates) to *enforcement*, all under a coherent legal framework that supports EU's competitiveness, from the market operator perspective.
- **Simplification potential** through digital-by-default compliance, machine-readable standards, clearer roles and faster decision-making, empowering authorities and businesses to act swiftly in a fast changing world.
- **Synergies in EU governance bodies:** economies of scale and mutualisation of resources to conduct executive tasks and oversee the product legislation framework.



European Product Act overview

Scope

- Rules for the establishment of **European standards and deliverables** in support of EU legislation for **products and for services**
- Rules for the **accreditation of conformity assessment bodies**
- Rules on **market surveillance** to ensure that only products compliant with EU rules are made available on the Union market (covering more than 70 pieces of EU harmonisation legislation).



Ambition

- The EPA will provide a **comprehensive, future-proof overhaul of the EU's approach to product legislation**
- It will revise, improve and better articulate the standardisation, conformity assessment, and market surveillance systems and promote **simplification and digitalisation**
- It will contribute to a **more competitive Single Market** and better balance the benefits of international e-commerce with the need to protect consumers, the environment, and the integrity of the EU's single market

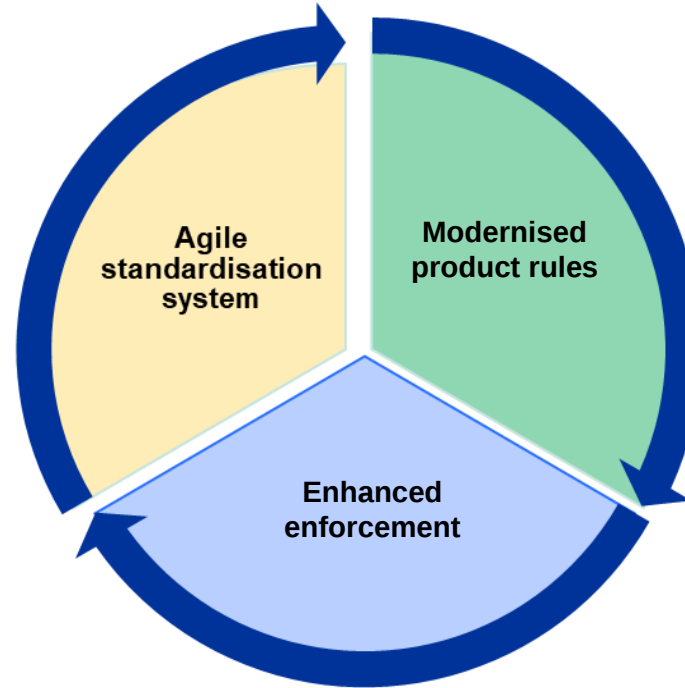
Improved Governance at EU level

- Enhanced **coordination** between standardisers, conformity assessment bodies and market surveillance authorities within the product's regulatory lifecycle.
- Possible **oversight** on conformity assessment and accreditation activities through direct intervention in illicit practices.
- **Intervention** in a limited number of important case of underenforcement with all necessary market surveillance tools.

European Product Act: key objectives by areas

Standardisation

- ✓ Increase the **responsiveness** of the Standardisation system to ensure delivery of the right standard at the right time, through improved flexibility, speed and inclusiveness of the ESS
- ✓ Improve **access and transparency** to standards in support of EU policy, to improve legal certainty
- ✓ Strengthen the **EU's position in international standardisation** to foster EU competitiveness



New Legislative Framework

- ✓ **Digitalise** product information to enable transparency, traceability, and informed choices.
- ✓ Establish a coherent, future-proof EU product framework to drive **circularity**.
- ✓ Reform **conformity assessment** systems to be more robust and agile.
- ✓ Accelerated procedures for **removal** of non-compliant products to protect consumers and ensure fair competition.

Market Surveillance

- ✓ Ensure **effective enforcement** of compliance for imported products, especially through **e-commerce**
- ✓ Promote efficient **cooperation and coordination** between authorities within and across MS
- ✓ Develop simplified and interconnected modern **IT tools**
- ✓ **Cost-effective and efficient** market surveillance authorities

Possible legal structures of the European Product Act

EPA as 1 single legal Act

1 single legal Act merging i) NLF, ii) Market Surveillance Regulation and iii) Standardisation Regulation

- Ensures higher legal consistency throughout the EU product framework
- Improves articulation between essential requirements and presumption of conformity through harmonised standards
- Enables single EU governance body for product legislation

EPA as 1 package with 2 legal Acts

1 package with 2 simultaneous legal Acts
i) revised Standardisation Regulation and
ii) one joint Act on Market Surveillance Regulation and NLF

- Allows to better take into account some specificities of the Standardisation Regulation notably its wider scope than product legislations (standards for services)
- Potentially less complex legally than 1 single Act
- Allows to better take into account different addresses of both Acts (market operators, national authorities, ESOs)

Both options are being reviewed in parallel; final choice based on results of Impact Assessments

- Introduction:
the Standardisation Regulation's revision
process

Better Regulation policy cycle



BR Key Instruments

- **Preparation & Adoption**
 - Planning & political Validation
 - Impact Assessments
- **Implementation & Application**
 - Evaluation and fitness checks
 - Compliance support tools
- **Horizontal Instruments**
 - SH consultation
 - Quality control



Procedural steps of the revision

- Planning and validation
- Call for evidence
- Public consultation
- Preparation of Impact Assessment report
- Regulatory scrutiny board
- Adoption of IA SWD and legislative proposal
- Publication of IA report
- Transmission to co-legislators



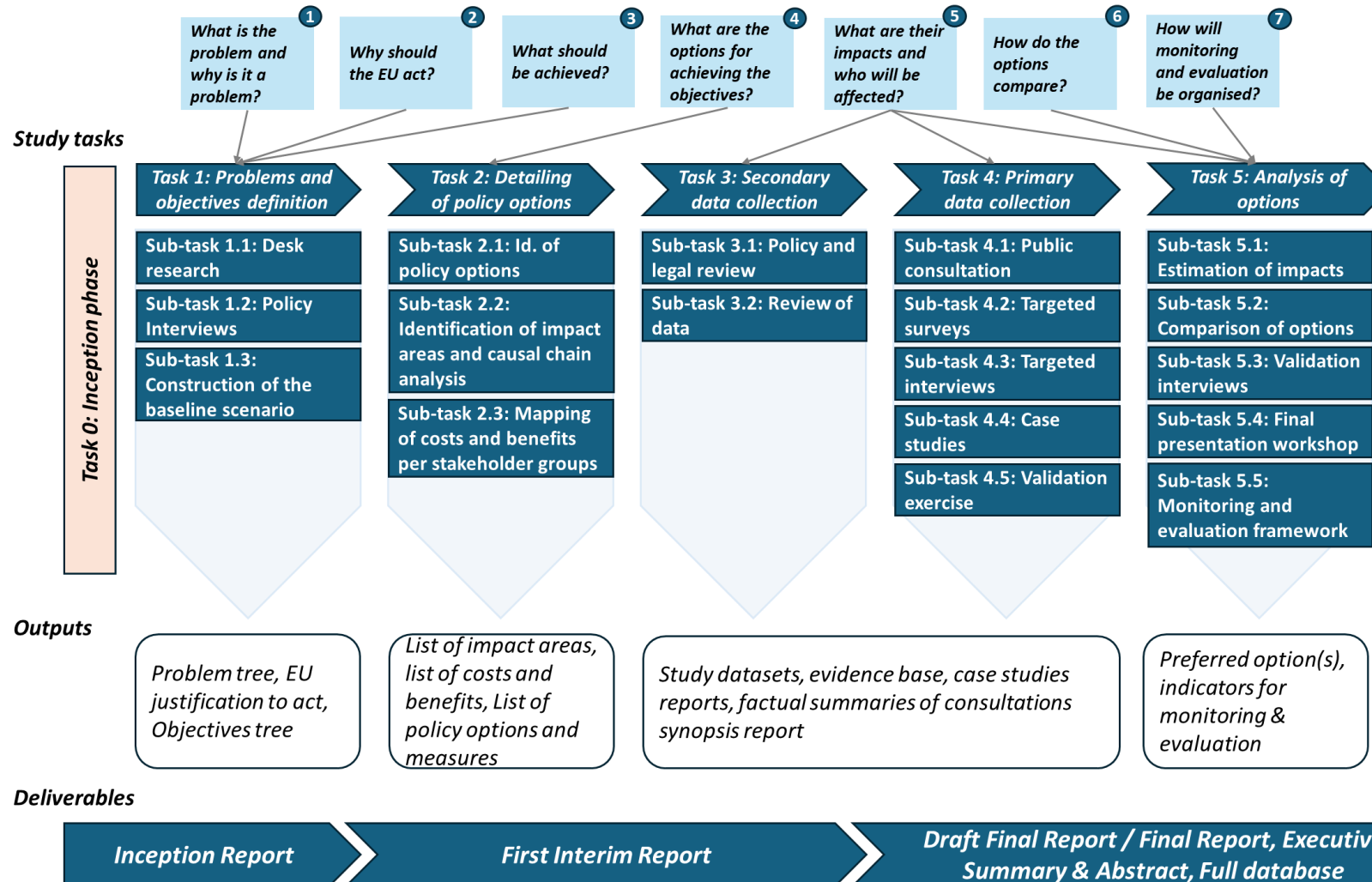
Impact Assessment

1. What is the problem and why is it a problem ?
2. Why should the EU act ?
3. What should be achieved ?
4. What are the various options to achieve the objectives ?
5. What are the impacts of the different policy options and who will be affected ?
6. How do the options compare ?
7. How would actual impacts be monitored and evaluated?

Impact assessment Study | Overview

The Study activities will follow the key Impact Assessment questions.

Key IA question (BRG, pg. 31-32)



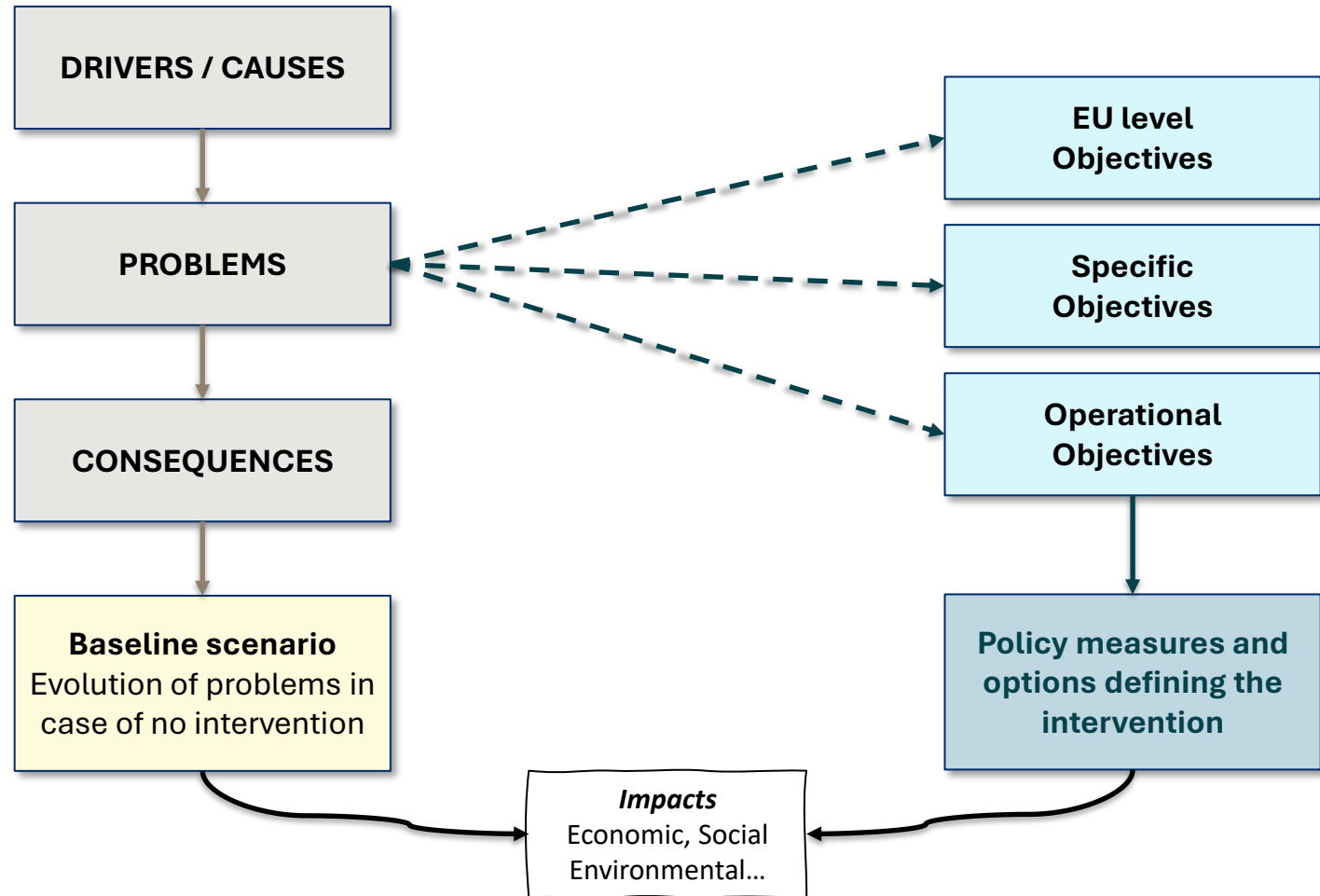
Impact assessment Study | Tasks 1 & 2 - from problems to options

The Study will examine the problems at stake, its causes and possible consequences.

Problems, drivers and consequences will be linked to the objectives of the review.

Activities envisaged

- ☐ Desk research
- ☐ Policy interviews
- ☐ Consolidate previous Evaluation results in a baseline scenario
- ☐ Mapping of relevant impacts areas to be measured and affected stakeholders



Impact assessment Study | Tasks 3 & 4: consultation activities

The Study will analyse information and stakeholders’ feedback on the expected effects of policy options, from available data, documents, and consultation activities

Activities envisaged

- Policy and legal review
- Review of existing datasets

-  Targeted surveys
-  1to1 interviews
-  Workshops/Focus groups

Stakeholder group	Policy interviews	Targeted Surveys	Gap-filing interviews	In-depth interviews	Case studies interviews	Validation interviews	Workshops
EU institutions							
MSA and national authorities							
International Standardisation Bodies							
European Standardisation Organisations (ESOs)							
NSBs / NCs / NSOs							
Annex III organisations							
Industry Association and companies							
Other industry consortia making standards							
Independent experts							

Impact assessment Study | Validation exercises

To ensure the robustness of results, different validation exercises will be organised throughout the different Study phases.

Validation exercises	Purpose
Workshop with the HLF 	Discuss problems and objectives
Virtual meeting with legal experts	
Validation interviews / Focus groups with key industry and societal representatives at EU level, including ESOs and Annex III organisations	Conduct reality check exercises with a panel of interviewees to validate the estimation of costs and benefits of the policy options
Final verification workshop with industry organisations and public authorities	Present and discuss the analysis and comparison of policy options with relevant stakeholder groups to be agreed with the Commission

Impact assessment Study | Timeline

The Study will follow DG GROW timeline and deadlines for the delivery of the Impact Assessment Report.



- Intervention logic and problem definition:
what do we need to improve?

Problem definition | the policy context

The European Commission has identified the need to modernise and **accelerate** the **European standardisation system** to better support **innovation**, **competitiveness**, and **inclusiveness**.

2022 Standardisation strategy

- Standards are at the heart of the **single market**, they provide **interoperability**, **compliance**, protection of **consumer** and **environment**
- Other countries are taking an **aggressive stance** towards standardisation **internationally**. The EU needs to have **international influence** to reduce dependencies
- The EU needs a **fast** and **leaner** system, so that the EU can be the **first mover** for critical **technologies**

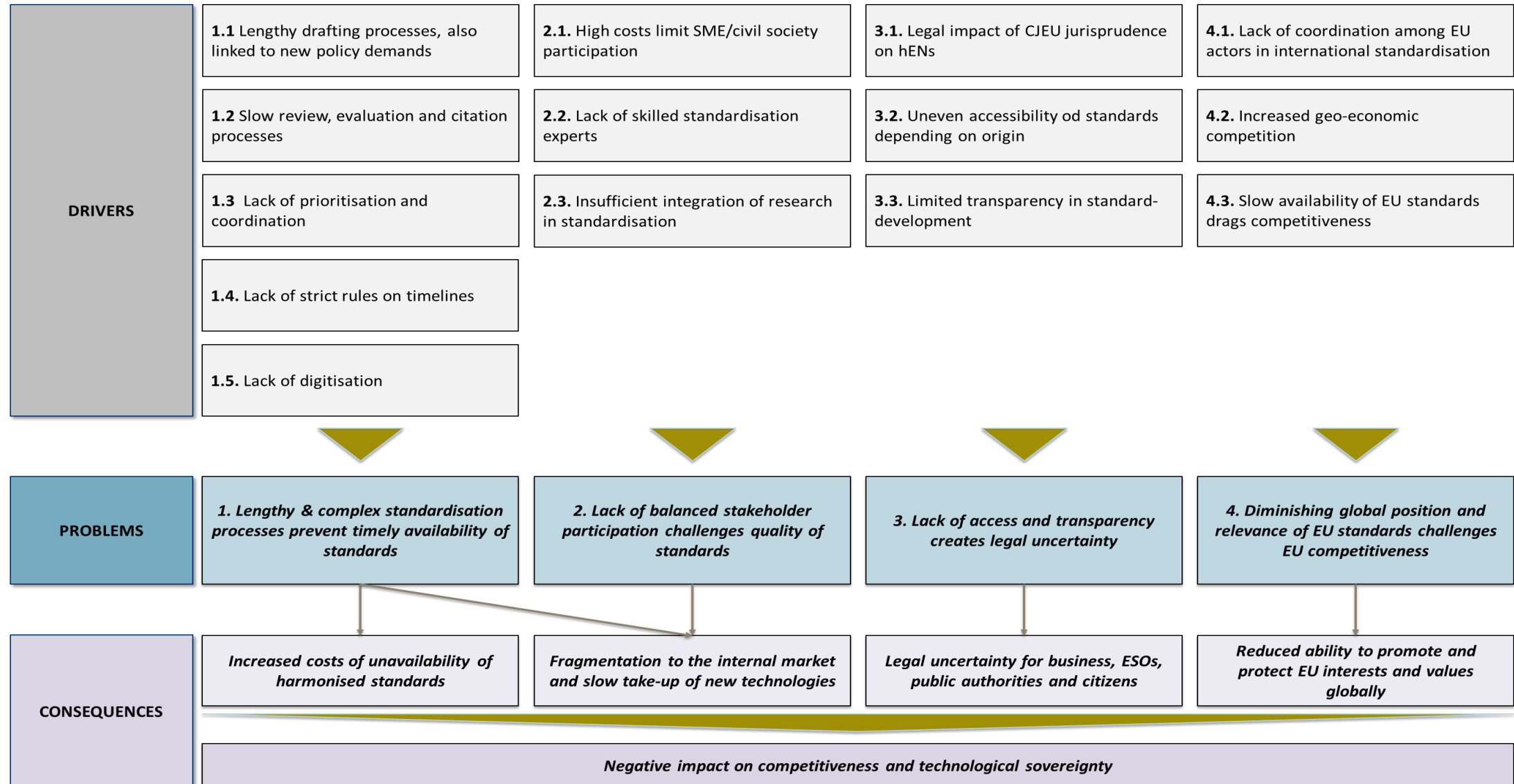
EU Competitiveness Compass (Jan 2025)

- Calls for **faster** and more **accessible** standard-setting processes, particularly benefiting **SMEs** and **startups**.
- Highlights the lack of **responsiveness** of current systems to **emerging technologies**.
- Stresses the need for **alternative mechanisms** ensuring legal certainty when harmonised standards are unavailable.

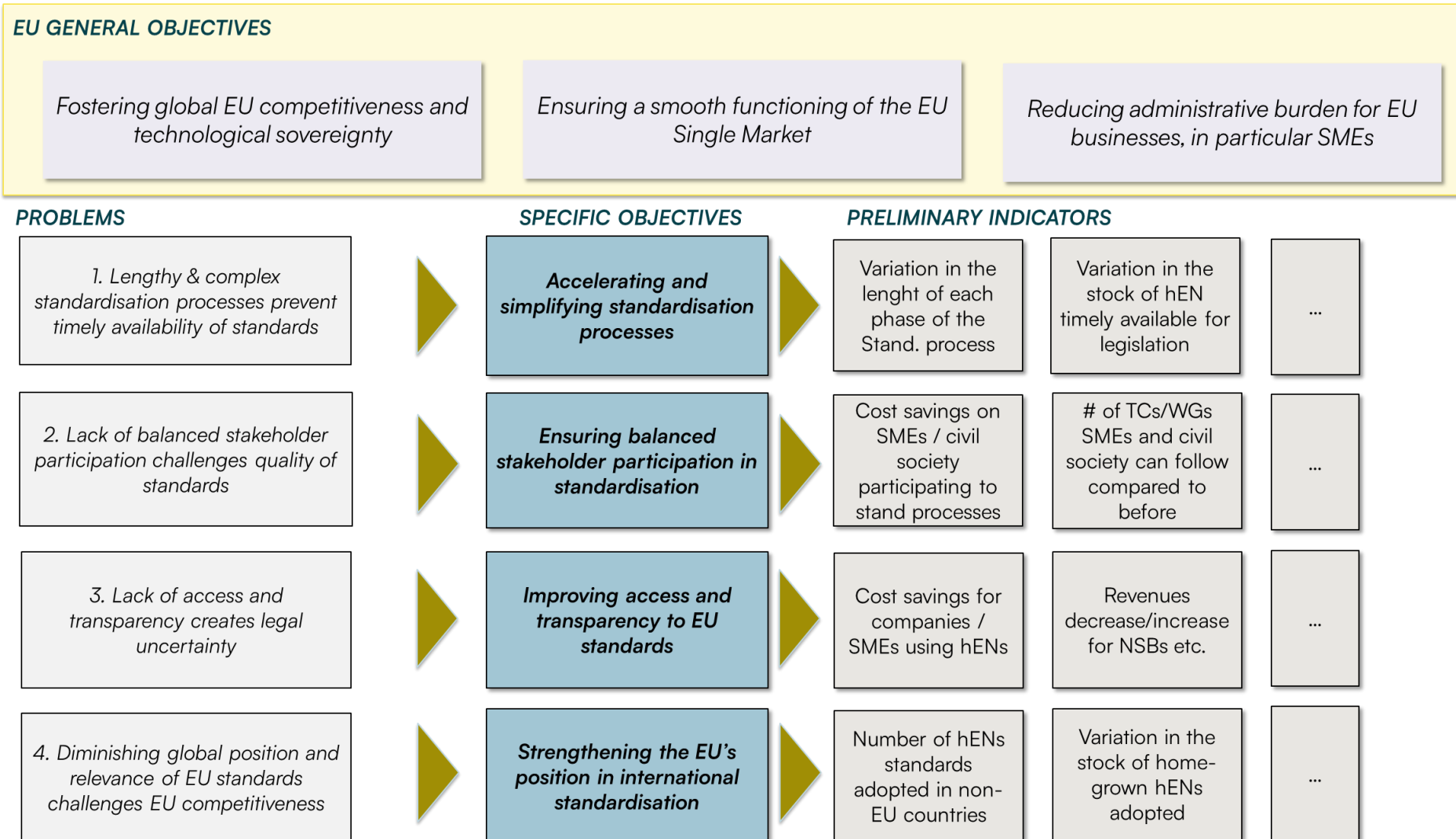
EU Single Market Strategy (May 2025)

- Commits to reviewing the Regulation to make the framework **future-proof**.
- The revision should aim to enhance **speed**, **flexibility**, and **balanced** stakeholder participation.
- In addition, it should seeks to improve **access** to **standards** and **reinforce** the **EU's global standard-setting role**.
- The revision will address the need to have **machine-readable** standards and to have a full **digitalisation** of standardisation processes.

Problem definition | analysis of problems



Problem definition | objectives





Intervention logic and problem definition: what do we need to improve?

Discussion

- | | | | |
|----|---------|-----|---------------|
| 1. | Italy | 7. | DIGITALEUROPE |
| 2. | Sweden | 8. | DigitalSME |
| 3. | ANEC | 9. | EHI |
| 4. | CEN | 10. | Orgalim |
| 5. | CENELEC | 11. | SBS |
| 6. | ETSI | 12. | T&D Europe |

coffee break
until 16.15



Policy options:
how can we improve the Standardisation
Regulation?



Policy options: how can we improve the Standardisation Regulation?

Discussion

- | | |
|-------------------|----------------|
| 1. France | 8. ECOS |
| 2. Germany | 9. ETUC |
| 3. CEN | 10. SBS |
| 4. CENELEC | 11. EHI |
| 5. ETSI | 12. SMEunited |
| 6. BusinessEurope | 13. T&D Europe |
| 7. DIGITALEUROPE | 14. EDA |

- Data needs to support the impact assessment

Data needs | call for contributions

Evidence we need to assess the impact of policy options.

○ **Market data on ENs / hENs:** what it is the cost of making one standard? What are the revenues from selling standards?
How are costs and revenues distributed?

○ **Use of standards:** how many companies in the EU and outside the EU use/buy ENs and hENs?

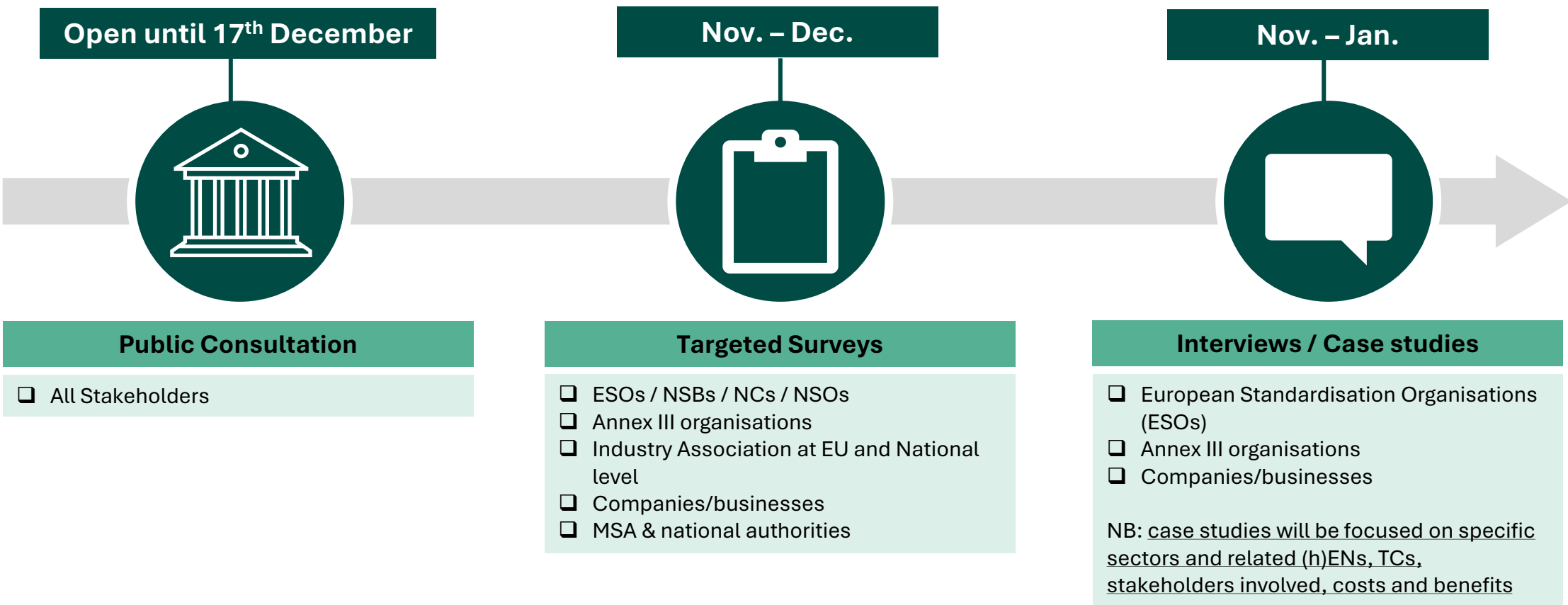
What we analysed so far...

- European Commission and EY *Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States* 2022, <https://ec.europa.eu/docsroom/documents/50114>
- SBS Experts Activity Report 2022
- Survey and interview data from a self-selected sample of around 30 companies / EU umbrella organisation covering all the hENs related sectors

What we need...

- ❑ Other studies / analyses you might have (e.g., the Roland Berger Study carried out for CEN in 2000)
- ❑ Support in the dissemination of the new surveys at national level and company level to ensure the widest possible audience
- ❑ Collaboration in the interviews we will arrange for case studies on specific sectors/hENs (on the identification of relevant TCs/WGs chairs, number of experts/companies involved, number of meeting held (offline/online) etc.)

Next steps



How to contribute?

Published on the Have Your Say portal.

[LINK](#)



We will send you the online survey link via email to collect your feedback and to allow you to share it with all potential respondents.



We will send invitations via email to stakeholder groups.



Data needs to support the impact assessment

Discussion

1. CEN
2. DIGITALEUROPE
3. T&D Europe

Thank you!

Useful links:

[Forum public webpage](#) on Europa website

[Forum WIKI home-page](#) restricted to Forum's members



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