



# ***Standardisation and Legislation:***

***A policy tool for the European institutions***

**Silvia Vaccaro  
Policy Officer  
DG GROW - Unit H.3**

## European standardisation ...

**...is founded on the WTO principles** of coherence, transparency, openness, consensus, voluntary application, independence from special interests, efficiency;

**...supports the Single Market** by eliminating technical barriers to trade, and facilitating the free movement of goods and services, network interoperability, means of communication, technological development and innovation.

# Standards – Market Tool

**Standardisation:** voluntary activity of private bodies, mostly without a direct regulatory link

- Most standards are developed on industry's initiative, by industry experts, for the use of industry, and using the financial resources of the industry
- European standards have a key role for the competitiveness of the European industry
- Economic contribution of standards to the economies of EU Members States: up to **1% of national GDP**



# What does the European Commission have to do with standardisation?

- **Coordinates standardisation policy** and cooperates with the different stakeholders
- Promotes use of European standards to **support EU legislation** and policies
- Prepares the **Annual Union Work programme**
- Formulates the **standardisation requests** to the European standardisation organisations (CEN, CENELEC and ETSI)
- **Funds** certain actors of the system

# European standards and EU legislation

**Enable EU  
INTERNAL  
MARKET**

**Instruments  
of EU POLICY**

**Protect EU  
CITIZENS**

# Standards in the EU

Standards support **European legislation and policies** for the:

- single market completion
- innovation and quality
- competitiveness and market access
- health and safety, environmental protection

*Remember: standards are **NOT** legislation!*

## **Standards:**

voluntary, consensual,  
developed by private  
organisations, revised every 5  
years, provide specifications  
and test methods  
(interoperability, safety,  
quality, etc.)

≠

## **Legislation:**

mandatory, imposed by law,  
developed by public authorities,  
revised when legislators decide,  
sets requirements to protect  
public interests

## EU legislation makes reference to Standards: HOW?

**Direct reference:** mandatory (the legislation imposes the product to meet the standard) - for specific use – exceptional

**Indirect reference (New Approach)** → legal text refers to publication of standards, **references published in the Official Journal of the EU**



## Main characteristics of the New Legislative Framework

- **Harmonise legislation** at EU level
- Use **standards** to translate essential **health & safety requirements** into technical specifications
- **Indirect reference**: legal text refers to publication of standards, standard references are published in the Official Journal of the EU
- The use of harmonised standards give **presumption of conformity**



# Regulation (EU) No 1025/2012 on European standardisation (1)

## Better communication & transparency for the European Commission:

- **Annual Union Work Programme** for European standardisation: planning future standardisation requests/mandates (Art. 8)

## Better **inclusiveness** of standardisation processes:

- Stakeholder participation in ESOs (Art. 5), including social actors
- SME access for NSBs (Art. 6)
- Participation of public authorities for Member States (Art. 7)

## Regulation (EU) No 1025/2012 on European standardisation (2)

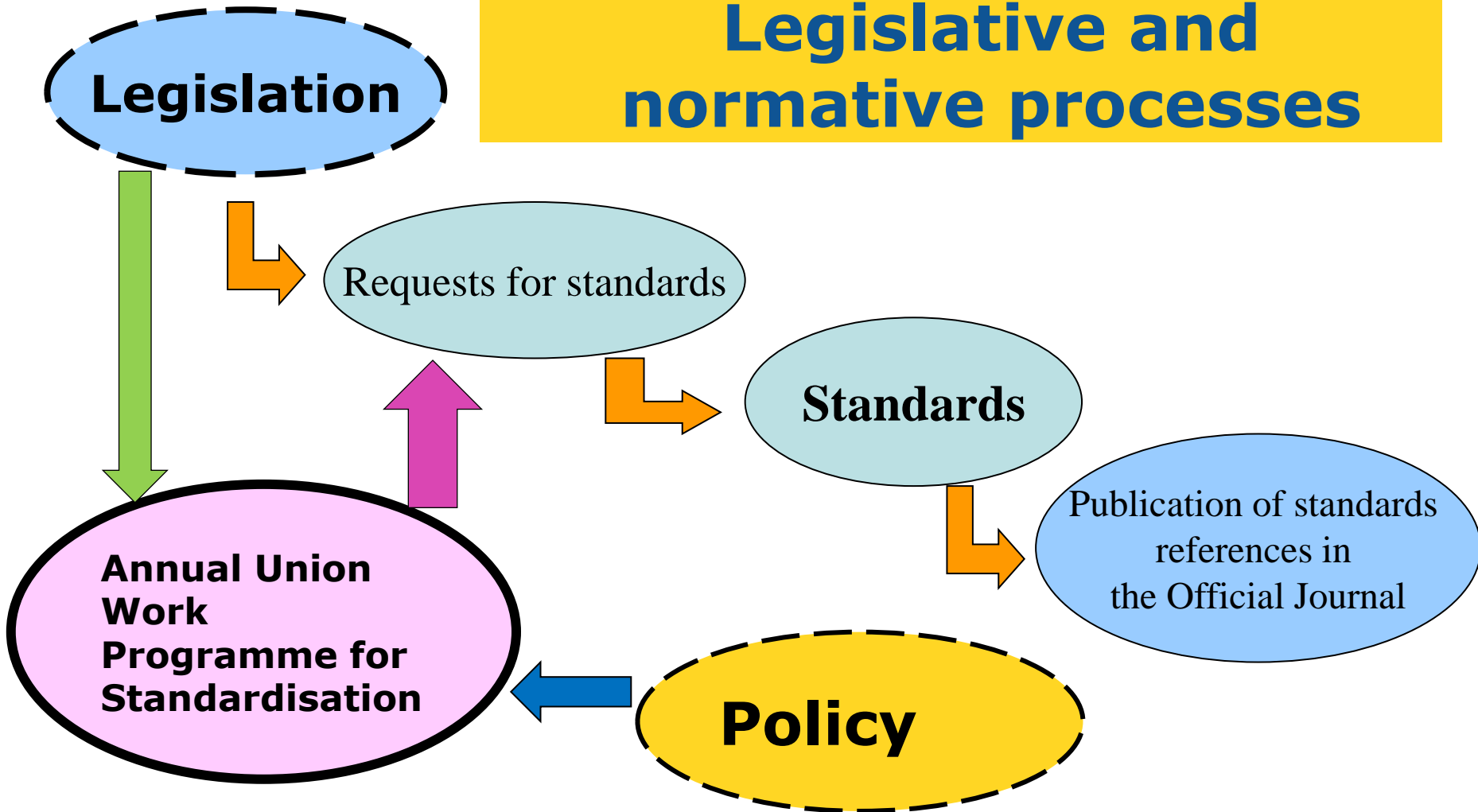
### Union financing of European standardisation:

- Financing European standardisation organisations (**ESOs**) - CEN, CENELEC and ETSI (operating grants and action grants) and National standardisation bodies (**NSBs**) (in case of joint actions with ESOs including translation of ENs)
- Financing **European level stakeholder organisations** meeting the criteria in Annex III (operating grants and action grants), including those representing **workers' interests**

# Inclusiveness of standardisation processes

- One of the unique aspects of European standardisation system
- Effective participation of Annex III organisations in standardisation, Regulation Art 5
  - **Opinion mechanism:** in CEN-CENELEC, whereby societal stakeholders' and SMEs' organisations who have signed a partnership agreement with CEN or CENELEC have the right to submit an Opinion on a (final) draft of a European standard before vote and adoption by CEN or CENELEC
  - **3SI Programme:** designed to increase the visibility of the societal stakeholders' and SMEs' interests in ETSI's standardisation activities

# Legislative and normative processes



## Regulation (EU) No 1025/2012 – requests for standards

### ***Standardisation requests are:***

- addressed to the ESOs (CEN, CENELEC, ETSI)
- in support of EU legislation and/or policies
- asking for European standards (ENs) or European standardisation deliverables
- for products and services



## How to identify harmonised standards (hEN)?

- **special category** of European standards
- **developed on the basis of a request** (mandate or standardisation request) from the Commission
- **developed by the ESOs**
- **assessed by the Commission** (compliance with the standardisation request and essential requirements)
- support application of the **Union's harmonisation legislation**
- involvement of Member States through the **Committee on Standards**
- compliant standards are cited in the Official Journal of the EU
  - Produces legal effects under the relevant EU legislation: **presumption of conformity** (part of Union law)
- Commission responsibilities in managing the process
  - Confirmed by the CJEU: **'James Elliott' case** (C-613/14)

## Update Standardisation Strategy of the European Commission 2021

- The Commission adopted a **new Industrial Strategy** in 2019 and an update this year:
  - to help Europe's industry lead the **twin transitions** towards **climate neutrality and digital leadership**.
  - its priorities are central also for the **recovery**
- Focus on **standardisation** as a tool for recovery geared to supporting green and digital transitions.
- Timeline subject to political validation (by the end of 2021).

# A coherent Framework



European Commission

L 316/12 **1025/2012** 14.11.2012

REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1473/2006/EC of the European Parliament and of the Council (text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardisation can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in products or services markets where compatibility and interoperability with other products or systems are essential.

(2) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. European standardisation reinforces the global competitiveness of European industry especially when established in coordination with the international standardisation bodies, namely the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products of higher and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole and consumers in particular. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing safety and value for consumers.

(3) European standards are adopted by the European standardisation organisations, namely CEN, Cenelec and ETSI.

(4) European standards play a very important role within the internal market for instance through the use of

EUROPEAN COMMISSION

**AUWP** Brussels 16/2016 COM(2016) 357 final

Standardisation package

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

The annual Union work programme for European standardisation for 2017

(SWD(2016) 185 final)



CoS – Committee on Standards



MSP – Multi-Stakeholder Platform



**European standards are voluntary and consensus-based**

**Standards support European policies and legislation**

**European Standardisation is a success story**

**DO NOT FORGET TO VISIT OUR  
WEBSITE:**

**[http://ec.europa.eu/growth/single-market/european-standards/index\\_en.htm](http://ec.europa.eu/growth/single-market/european-standards/index_en.htm)**

**Any questions?  
GROW-H3@ec.europa.eu**



European  
Commission

