



Star4bbs

Standards and R&I projects: how to support the bio-base industries

Standardization world in a nutshell

14th December, 2024



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1. Standardization: role and vision





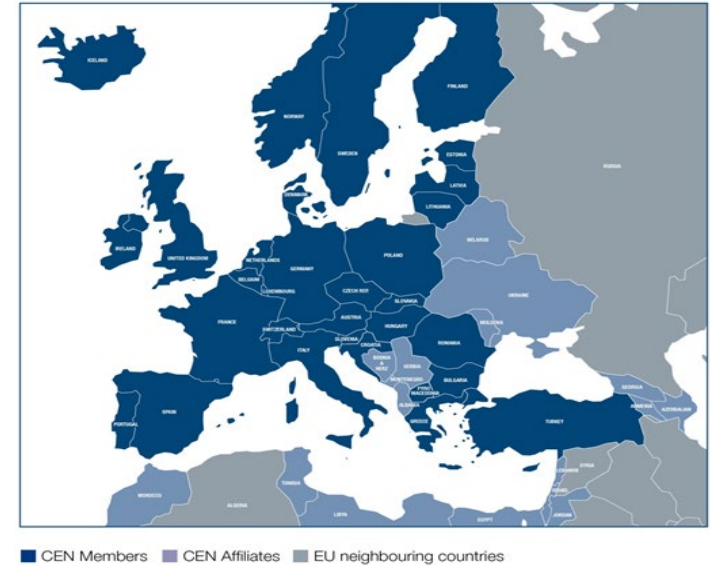
About UNI – Italian Standardisation Body

- Set up in 1921, UNI is a private, **not-for-profit association**
- Entitled to develop standards and best practices (“prassi di riferimento”) in Italy covering all industrial, trade and service sectors (except for the electric and electronic one)
- An open platform working together with all stakeholders: industries, professionals, sectorial associations, public bodies, research centers, academia
- Recognized by **EU Regulation 1025/2012** on European Standardisation and the Italian Legislative Decree 223/2017
- Represents Italy in European and International standardization contexts



ABOUT CEN – European Committee for Standardization

- ✓ Provides a **multistakeholder platform** for the development of **European Standards** and other technical documents in relation to various kinds of products, materials, services and processes
- ✓ Help to ensure that the system **respects the WTO principles of transparency, openness, coherence, consensus**
- ✓ Based on the **national pillars**, which are the National Standardization Bodies or the members of CEN
- ✓ Supports the **EU Legislator** on specific requests





CEN – FIGURES






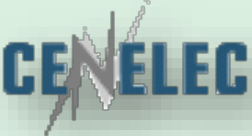







■ CEN Members ■ CEN Affiliates ■ EU neighbouring countries

- **34 national Member countries:** national standardization bodies
- **6 Affiliates** (Albania Bosnia and Herzegovina Georgia Moldova, Republic of Montenegro Ukraine)
- **17 Companion Standardization Bodies** (es. Australia, Canada, Egypt, Israel, Tunisia ...)
- **10 Partner Organizations** (es. ANEC, ECOS, ETUC, SBS ...)
- **International cooperation with ISO**
- **200.000 Experts**
- **495 Technical Committees**
- **17.908 Published standards**



Standards Bodies @ International, European and National (Italian) level

	Electronics	Telecommunications	All the remaining sectors	<u>LEGAL BASIS</u>
				n.a.
				EU Regulation 1025/2012
				Legislative Decree 15 December 2017 n.223



STANDARDISATION AND THE UN GOALS FOR THE 2030 AGENDA



Contributions of standardization to the SDGs

Economic: they facilitate international trade, improving a country's "National Infrastructures for Quality" and supporting sustainable business practices.

Social: they help to improve the health and well-being of citizens. They concern all aspects of social well-being, from health systems and products to social inclusion and accessibility.

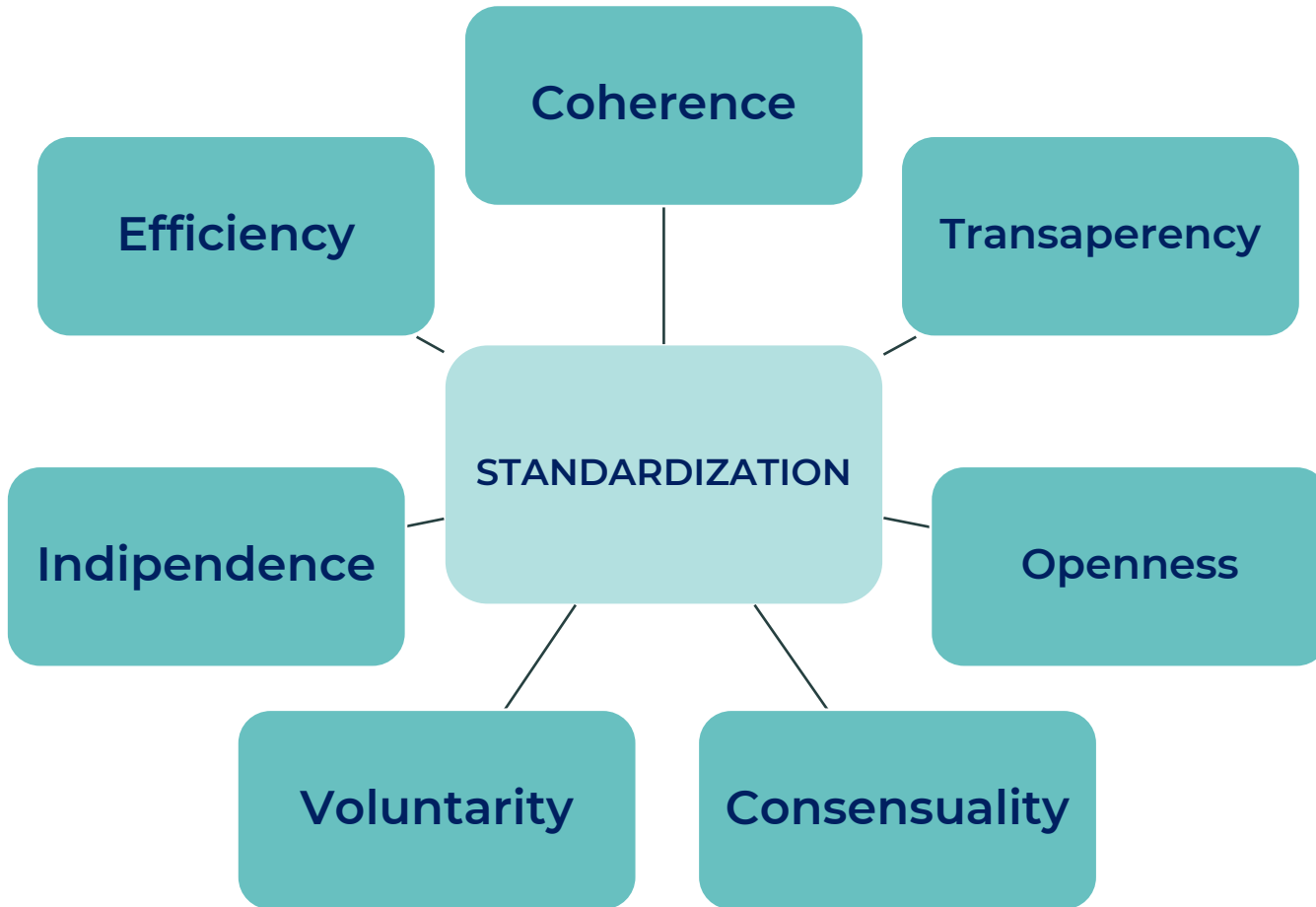
Environmental: they help to manage the environmental impact of all activities. They deal with aspects such as building an environmental management system, measuring and reducing greenhouse gas emissions and energy consumption, as well as encouraging responsible consumption.



But also ... **institutional sustainability** because standardisation facilitates public-private dialogue and supports **Public Private Partnership** activities.

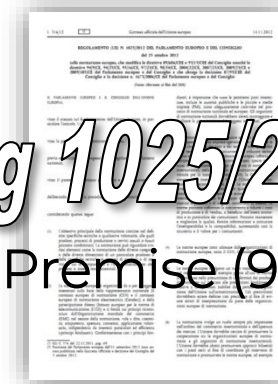


Standardization values



Reg 1025/2012

Premise (9)



*To ensure the effectiveness of the rules and regulations which strategic tools for the Union **it is necessary to be able to rely on an effective and efficient standardization system,** which provides a flexible and transparent platform to reach consensus among all participants and that it is financially sustainable.*



WHAT IS A STANDARD?

- **Technical document** designed to be used as a **rule, guideline or definition**. It is a **consensus-built, repeatable** way of doing something. Standards are created by bringing together **all interested parties** such as **manufacturers, consumers** and **regulators** of a **particular material, product, process or service**. All parties benefit from standardization through increased product **safety** and **quality** as well as lower transaction costs and prices.
- **Implemented by the national CEN Members** as a national standard, and therefore is included in the standards catalogue of CEN and CENELEC's Members, the National Standardization Organizations in **34 countries**.



The standardization deliverables

1

Technical standard

- Prescriptive document
- Consolidated «state of the art»
- Review every five years

EN, EN ISO,
ISO, DIN,
UNI...

2

Technical Specification

- Prescriptive document **TS**
- State of the art in progress
- Periodic review

3

Technical Report

- Informative document **TR**
- Preparatory to future standardization activities
- Periodic review

4

«Light» standard

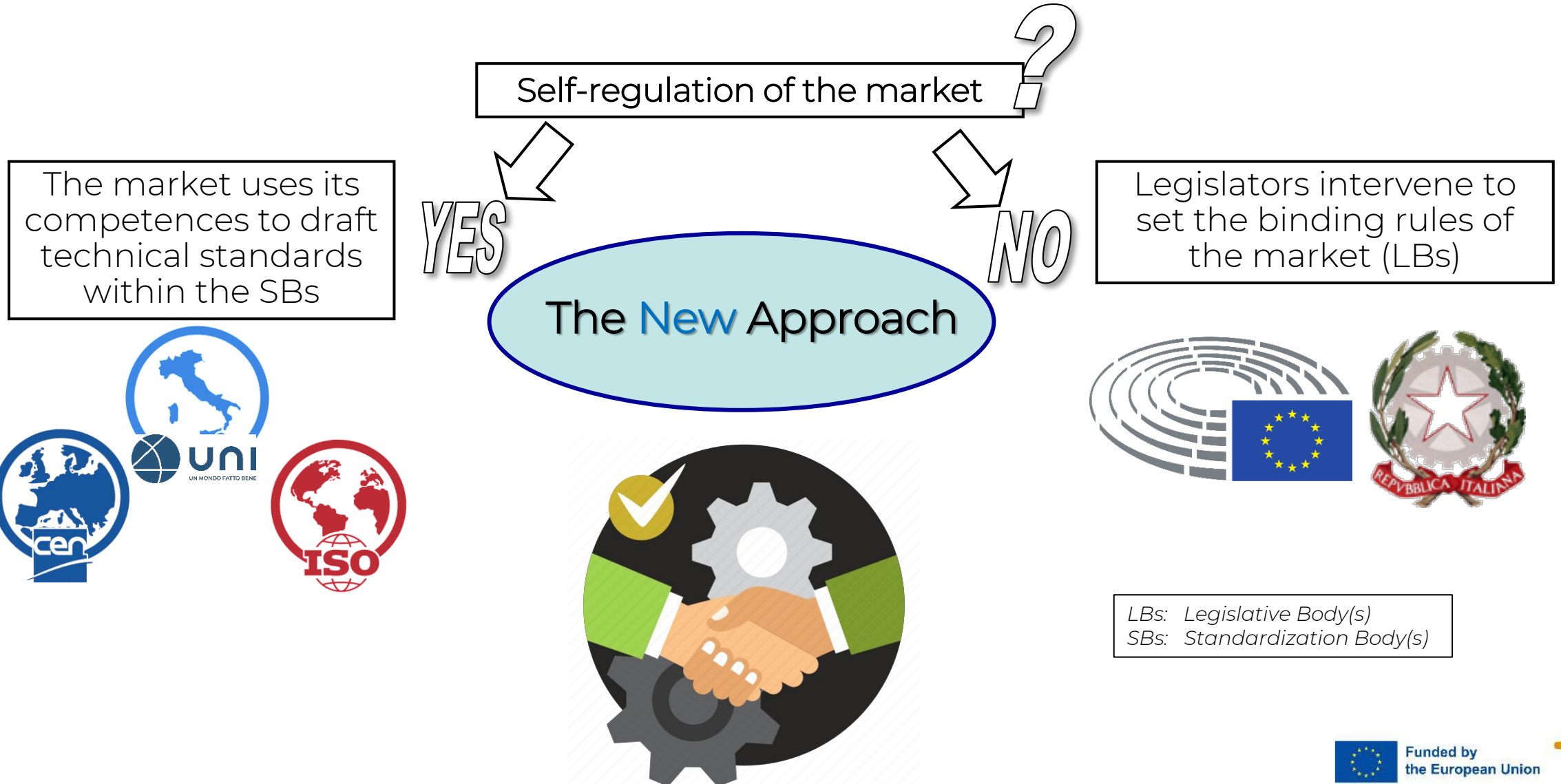
- Pre-standard with restricted consensus
- Preparatory to future standardization activities
- Shorter review period

CWA, IWA, PdR,
PAS, SPEC...



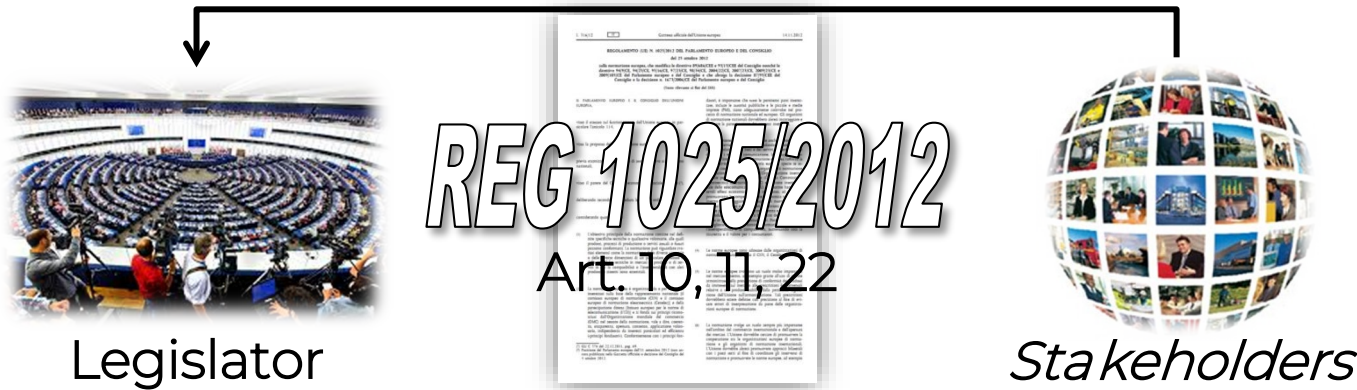


Standardisation and Legislation

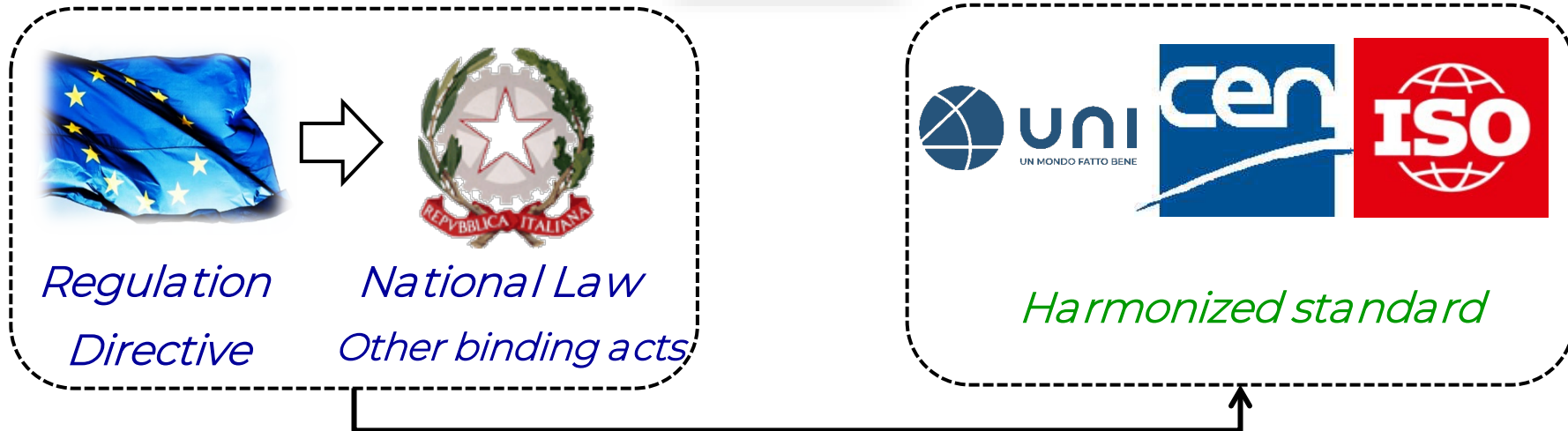




Standardisation and Legislation: the Standardization Request and harmonized standards



harmonised standard:
means a European
standard adopted on the
basis of a request made by
the Commission for the
application of Union
harmonisation legislation
(Regulation EU 1025/2012)



Essential Requirements

Technical Requirements

**Standardization Request
(mandate)**



New Legislative Framework (NLF)



To improve the internal market for goods (...) on the EU market, **the new legislative framework was adopted in 2008.**

It is a package of measures that aim to improve market surveillance and boost the quality of conformity assessments. It also clarifies the **use of CE marking** (...)

- **Regulation (EC) 765/2008** setting out the requirements for accreditation and the market surveillance of products;
- **Decision 768/2008/EC** on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation;
- **Regulation (EU) 2019/1020** on market surveillance and compliance of products





DIRECTIVES AND REGULATIONS: New Legislative Framework (NLF)

- Toy Safety - Directive 2009/48/EU
- Transportable pressure equipment - Directive 2010/35/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- **Construction products - Regulation (EU) No 305/2011**
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Non-automatic Weighing Instruments - Directive 2014/31/EU
- Measuring Instruments - Directive 2014/32/EU
- Lifts - Directive 2014/33/EU
- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU
- Marine Equipment - Directive 2014/90/EU
- Cableway installations - Regulation (EU) 2016/424
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746
- **EU fertilising products – Regulation (EU) 2019/1009**
- Drones - Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems



Mandates and harmonised standards on bio-based products (1)

Directive 94/62/EC on packaging and packaging waste

EN 13428 Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction

EN 13429 Packaging - Reuse

EN 13430 Packaging - Requirements for packaging recoverable by material recycling

EN 13431 Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value

EN 13432 Packaging - Requirements for packaging recoverable through composting and biodegradation.

M/317 - Second standardization mandate to CEN related to the packaging and packaging waste directive 94/62/EC





Mandates and harmonised standards on bio-based products (2)

Commission's Lead Market Initiative between 2008 and 2011

CEN/TC 411 - BIO-BASED PRODUCTS

- M/429 for the elaboration of a standardisation programme for bio-based products
- M/492 for the development of horizontal standards for bio-based products

- CEN/TR 16721 Bio-based products – Overview of methods to determine the bio-based content
- EN 16640:2017 - Bio-based products - Bio-based carbon content - Determination of the bio-based carbon content using the radiocarbon method
- EN 16575 Bio-based products – Vocabulary
- CEN/TS 16766 Bio-based solvents – Requirements and test methods
- EN 16785-1 Bio-based products – Bio-based content – Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis
- EN 16751 Bio-based products - Sustainability criteria



UNI/PdR 135:2022 Bio-based products - Organization and product application guidelines for environmental and social qualification

SCOPE

This UNI/PdR provides application guidelines for the environmental and social qualification of bio-based products by taking their life cycle into consideration, with sustainability assessments, at both organization and product level. The guidelines can be used for benchmarking, eco-design and sustainability qualification, also in relation to the achievement of the UN Sustainable Development Goals (SDGs).

The development of reference values for metrics and evaluation schemes are outside the scope of this UNI/PdR. In line with UNI **EN 16751**, it does not apply to the following categories of bio-based products: food, feed and energy. This document does not apply to products whose specific characteristics (see UNI EN ISO 22095) are allocated solely by credit or other means of transferring intangible characteristics.



2. Standardization and certification (conformity assessment)





CONFORMITY ASSESSMENT AND TYPES OF AUDITS

Table 1 — Different types of audits		
1st party audit	2nd party audit	3rd party audit
Internal audit	External provider audit	Certification and/or accreditation audit
	Other external interested party audit	Statutory, regulatory and similar audit



PROPERTY SCHEME

- Owned by companies/ associations/other entities
- Expression of a narrow consensus base
- Might be strongly driven by a single party-based interests
- No legal basis applicable

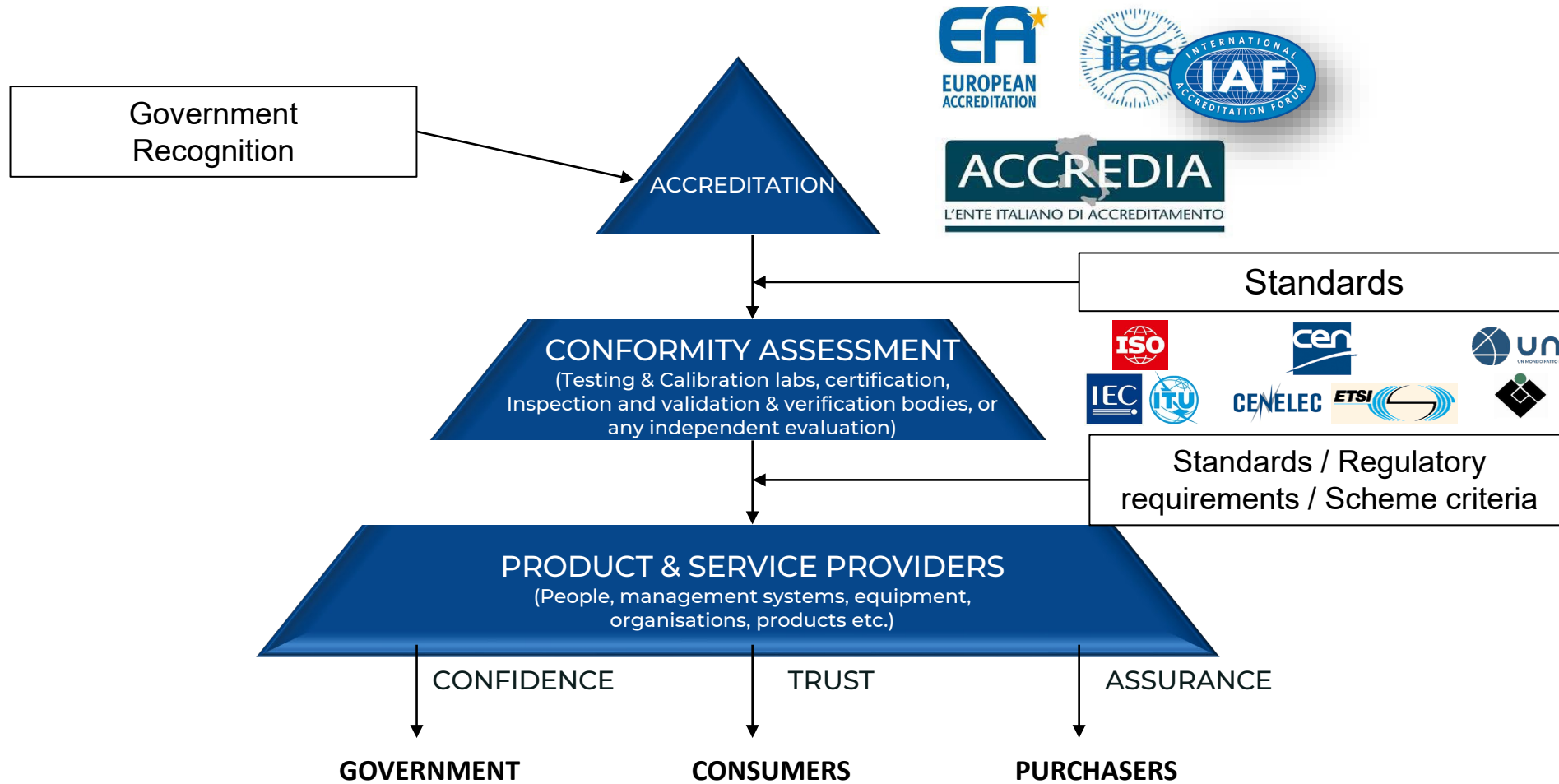


STANDARDS

- Open and **transparent** process
- Broad **consensus-based** approach
- Applicable **legal basis**
- Third party **interests are mitigated** within the technical bodies drafting the standard
- **Multi-stakeholder platform**
- **Possible citation** in legislative documents



The Accreditation Pyramid = Quality Infrastructure System (QIS)



Useful link: [UNIDO](#)

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Thank you for your attention!



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