Council of the European Union
General Secretariat

Interinstitutional files:
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LIMITE

SIMPL	**ECO**	**COMPET**
ANTICI	**ENT**	**ENV**
EF	**IA**	**CLIMA**
ECOFIN	**IND**	**TRANS**
MI	**TELECOM**	**ENER**
	POLCOM	**CODEC**

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus IV - Digitalisation and Common Specifications - Commission presentation

Delegations will find attached an updated version of the presentation on the Omnibus IV - Digitalisation and Common Specifications prepared by the Commission for the meeting of the Antici Group (Simplification) of 16 June 2025.

Common Specifications

Simplifying Compliance in the Single Market

- The Omnibus package helps businesses comply with EU legal rules when harmonised standards are not available.

- **How it Works**:
  - ✓ The Commission aligns a fall-back option: *common specifications* for businesses to follow.
  - ✓ Businesses use these specs to prove they meet EU requirements.

- **Simplification brings**:
  - ✓ Legal certainty (legal effect: *presumption of conformity*)
  - ✓ Less costs for businesses
  - ✓ Alignment with existing legal framework:
    - Common specifications already exist in +10 legislative acts.
    - Proposal to align 16 additional directives/regulations.
  - ✓ Consistent rules for businesses across sectors.
  - ✓ Addressing challenges:
    - unavailability of draft harmonised standards based on ISO/IEC for 15 months
    - mandatory legal dependency on European standardisation organisations
    - dependency on ISO/IEC standards (28% of CEN, 67% of CENELEC hENs)
    - delays in standards development

Savings from common specifications

I. Overview of Benefits (total for standardisation) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Compliance cost reduction resulting from the availability of common specifications	On average 4 000 EUR per product, which would have required certification in the absence of a harmonised standard.	The figure given is not an aggregated one. It represents the amount for a single conformity assessment of one individual product (placed on the market) in the absence of harmonised standards and when no alternative option exists for using the presumption of conformity (i.e. common specifications) under one of the legislative acts covered by the proposal. On top of this, the business would avoid costs related to legal uncertainty and finding alternative methods to demonstrate compliance, which cannot be quantified.

Source: SWD(2025)130 - Commission staff working document accompanying COM(2025)503 and COM(2025)504, p. 23.

Legal aspects

March 2024: Landmark CJEU Ruling

The Court of Justice of the European Union (Grand Chamber) ruled in case C-588/21P (*Public.Resource.Org and Right to Know v Commission and Others*) that the Commission must grant access to harmonised standards under the *Access to Documents Regulation (EC) 1049/2001*.

Consequences:

- *System Disruption:* Eligible standards are now accessible for *free* to citizens and businesses.
- *Ongoing Dispute*: The International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) have brought a case (T-631/24) against the Commission in December 2024.
- *Non-availibility:* Over 100 harmonised standards based on ISO/IEC standards have not been delivered since March 2024.
- *Legal uncertainity*: Although the relevant EU legislation is applicable, the necessary standards to support its implementation are not available.

Average length to develop hENs

Phase	Subphase	Average duration (2024)
Phase A	**Standardisation requests adopted by the European Commission**	1 year and 8 months
Phase B	**Acceptance of standard request by the ESOs**	1 month
	Drafting	3 years and 1 month
Phase C	**ESO submission time to EC after standard reference adoption**	3 months
	Citation time in the OJEU	11 months
Total		**6 years and 1 month**

Source: *Evaluation Study of the Regulation (EU) 1025/2012 on European Standardisation*

Why is the wording not alligned with the Machinery Regulation?

- Commission Implementing **Regulation (EU) 2020/1207** regarding common specifications for the reprocessing of single-use devices
  - **Date of application:** 26 May 2021
- Commission Implementing **Regulation (EU) 2022/1107** laying down common specifications for certain class D in vitro diagnostic medical devices
  - **Date of application:** 25 July 2022
- Commission Implementing **Regulation (EU) 2023/1194** regarding transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
  - **Date of application:** 22 June 2023

Development of CSs under Medical Devices Reg.

1) Preliminary discussion in the concerned thematic subgroup of the sectoral expert group, the Medical Device Coordination Group (MDCG) – *Art. 103 of Regulation (EU) 2017/745*

- the In vitro diagnostic medical devices (IVD) Subgroup (Working Group 11)
- the "Annex XVI" products Subgroup (Working Group 13)

2) Creation of a technical group within the subgroup, *with experts from the competent authorities of the MS and sectorial stakeholders*

3) Preparation and presentation of final draft CS to Subgroup for endorsement

4) Submission of CS to the MDCG for endorsement

5) Launch of the adoption procedure: inter-service consultation, translation, adoption, publication in the *Official Journal of the European Union* (OJEU) with the appropriate transitional, entry into force and application provisions.

6) Committee on Medical Devices adopts CS – *Art. 114 Reg. (EU) 2017/745 and 2017/746*

In vitro diagnostic medical devices Subgroup

Members	
Austria	Ireland
Belgium	Italy
Croatia	Lithuania
Cyprus	Luxembourg
Czech Republic	Netherlands
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	
Sweden	

Observers	
Biomedical Alliance in Europe (the BioMed Alliance)	Professionals' Associations
European Association Notified Bodies Medical Devices (Team-NB)	Trade and business associations
European Association of Authorised Representatives (EAAR)	Trade and business associations
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)	NGOs
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Trade and business associations
MedTech Europe (MTE)	Trade and business associations
Notified Body Coordination Group - Medical Devices (NBCG-Med)	Other organisations
Directorate of Health - Norway	Third country
Icelandic Medicines Agency	Third country
Medicines and Medical Devices Agency - Turkey	Candidate country

In vitro diagnostic medical devices Subgroup

Members	
Austria	Ireland
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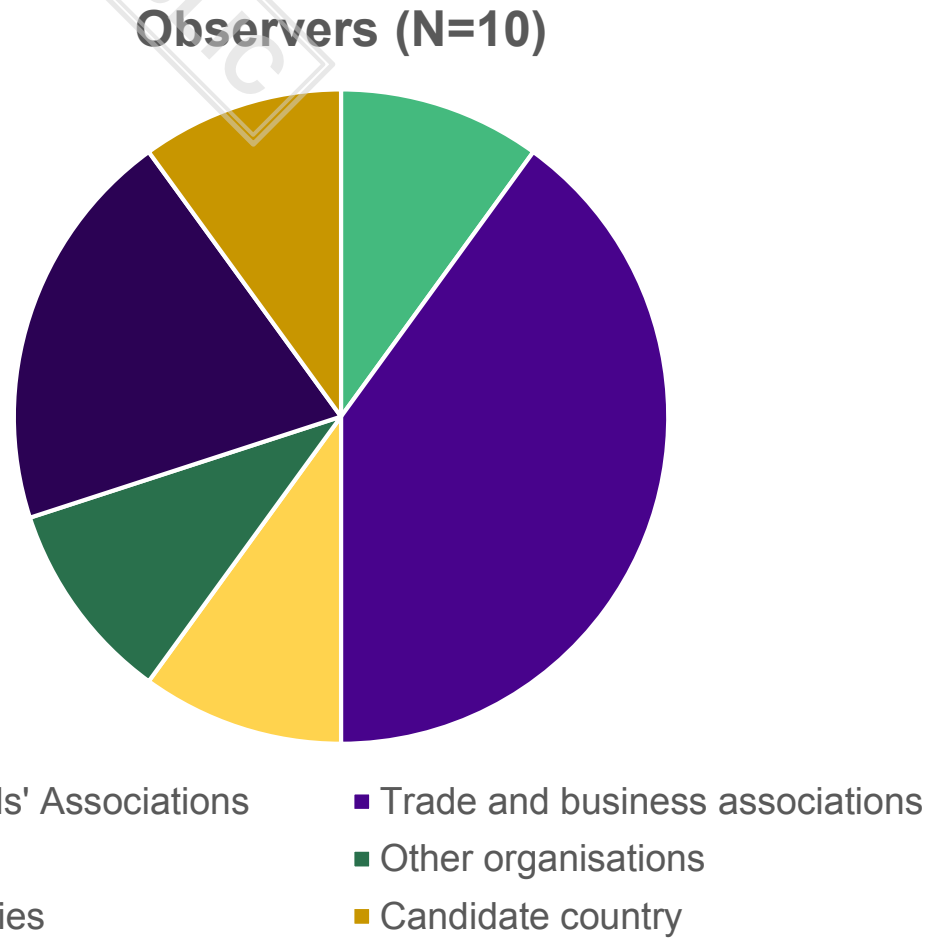
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	
Sweden	



"Annex XVI" products Subgroup

Members:
Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Ireland
Luxembourg
Netherlands
Poland
Portugal
Slovakia
Slovenia
Spain
Sweden

Observers:	
APPLiA (Home Appliance Europe) (APPLiA)	Trade and business associations
Association of the European Self-Medication Industry (AESGP)	Trade and business associations
EUROM1	Trade and business associations
EUROMCONTACT	Trade and business associations
European Association Notified Bodies Medical Devices (Team-NB)	Trade and business associations
European Association of Authorised Representatives (EAAR)	Trade and business associations
European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR)	Trade and business associations
European Council of Optometry and Optics (ECOO)	Professionals' Associations
European Healthcare Distribution Association (GIRP)	Trade and business associations
MedTech Europe (MTE)	Trade and business associations
Notified Body Coordination Group - Medical Devices (NBCG-Med)	Other Organisations
SMEunited aisbl (SMEunited)	Trade and business associations
Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (ZVEI)	Trade and business associations
Directorate of Health – Norway	Third country
Icelandic Medicines Agency	Third country
Medicines and Medical Devices Agency – Turkey	Candidate country
Ministry of Health – Linchenstein	Third country

“Annex XVI” products Subgroup

Members:

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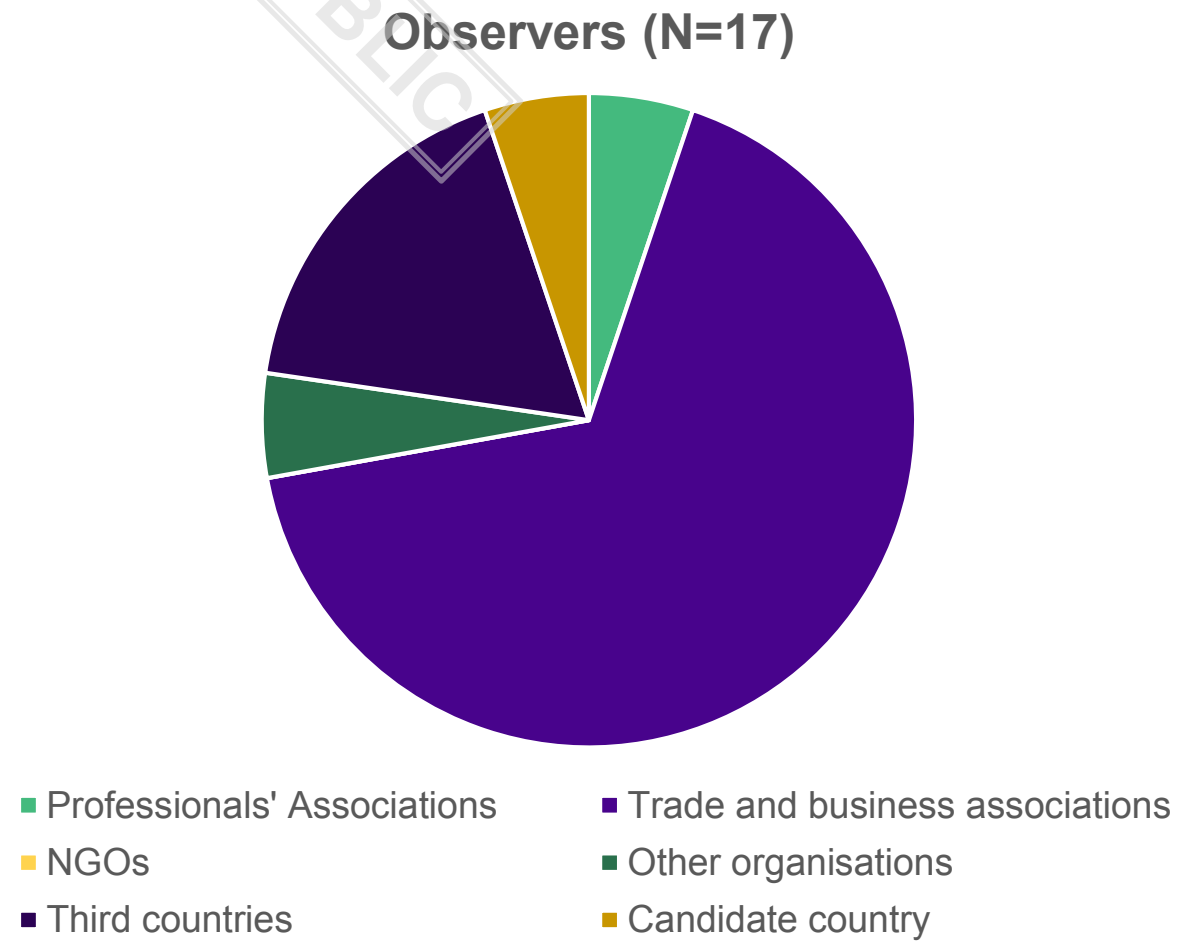
Croatia	Poland
Czech Republic	Portugal
Denmark	Slovakia
Estonia	Slovenia
Finland	Spain
France	Sweden
Germany	



What is an “urgent concern”?

Case study: Heat pumps - Delays risk market innovation and green transition

Legislation: 2006/42/EC (Machinery Directive), 2014/35/EU (Low Voltage Directive)

Standardisation Request: M/511

IEC 60335-2-40:2018 → EN IEC 60335-2-40:2023 **(5 yrs delay)**
IEC Publication: 26.01.2018 → **Available by ESO:** 05.05.2023

IEC 60335-2-40:2022 → EN IEC 60335-2-40:2024 **(2 yrs delay)**
IEC Publication: 05.09.2022 → **Available by ESO**: 08.11.2024

Machinery Regulation (EU) 2023/1230 – Art. 20

3. The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation.

Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and:

(i) the request has not been accepted; or

(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or

(iii) the harmonised standards do not comply with the request; and

(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

What is the scope of the proposals? Why is Reg. 765/2008 included?

- **List of amended legislative acts**

1. Recreational craft and personal watercraft - Directive 2013/53/EU
2. Simple Pressure Vessels - Directive 2014/29/EU
3. Electromagnetic Compatibility - Directive 2014/30/EU
4. Non-automatic Weighing Instruments - Directive 2014/31/EU
5. Measuring Instruments - Directive 2014/32/EU
6. Lifts - Directive 2014/33/EU
7. ATEX - Directive 2014/34/EU
8. Low Voltage - Directive 2014/35/EU
9. Radio equipment - Directive 2014/53/EU
10. Pressure equipment - Directive 2014/68/EU
11. Marine Equipment - Directive 2014/90/EU
12. Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU

1. Cableway installations - Regulation (EU) 2016/424
2. Gas appliances - Regulation (EU) 2016/426
3. Personal protective equipment - Regulation (EU) 2016/425
4. Requirements for accreditation and market surveillance relating to the marketing of products - Regulation (EU) 2008/765

Stakeholder views

April 2025 Industrial Forum Survey (N=96)

- Absence or delayed publication of hENs leads to higher costs and administrative burden.
- Stakeholders recommend improving legal clarity and mutual recognition of alternatives to hENs.

2024 Public consultation for *Standardisation Regulation* Evaluation (N=254)

- hENs support EU cross-border activities and trade (72% of respondents), but current standard-development process is inefficient (52%).
- For some stakeholders, technical or common specifications should be used only as a last resort.

Any Questions ?

Thank you !