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From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus IV - Simplification on digitalisation and common specifications - Commission presentation

Delegations will find attached a presentation on the Omnibus IV - Simplification proposals on digitalisation and common specifications prepared by the Commission for the meeting of the Antici Group (Simplification) of 6 June 2025.

Omnibus on digitalisation and common specifications

Antici Group on Simplification - 6 June

Omnibuses on digitalisation and common specifications

- In its Communication on *‘Long-term competitiveness of the EU: looking beyond 2030’*, the Commission committed to a dedicated effort to **rationalise and simplify reporting requirements and administrative burdens**.
- Moreover, the Communication *‘A Competitiveness Compass for the EU’* highlights that **digitalisation goes hand in hand with simplification** to reduce reporting burdens and identified the need to seek for **alternative options to give businesses legal certainty regarding compliance with EU rules** in situations where harmonised standards do not exist, are not available, are not sufficient, or there is an urgent need.



Omnibuses on digitalisation and common specifications

This omnibus package aims at amending most of the harmonisation products legislation under the New Legislative Framework.

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications



Digitalisation



Digitalisation of the EU declaration of conformity

- The proposals include the **digitalisation of the EU declaration of conformity** – to avoid any unnecessary accompanying paper documentation:
 - The EU declaration of conformity will need to be **drawn up in electronic form**;
 - For Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230 and Directives 2000/14/EC, 2013/53/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU and 2014/53/EU which foresee that the EU declaration of conformity must **accompany the product**, the EU declaration would need to be **made accessible through an internet address or machine-readable code**.



Introduction of the digital contact and digitalisation of all communication



- The introduction of a **digital contact** will facilitate communication between economic operators and national authorities or end-users. Manufacturers and other economic operators will become **easily reachable**.
- All **references to paper** have been deleted.
- **Digitalisation** of **all communication** between economic operators, national authorities or end-users.

Digital instructions - General



The instructions accompanying products may be provided in **electronic form** with the exception of **safety information** which should be provided on paper or marked on the product for consumers.



The digital instructions would need to be **accessible online** during the expected lifetime of the product and for at least 10 years (or more depending on the legislation).



If instructions are provided in electronic form, the end-users will have **the right to request a paper version** of the instructions and safety information at the time of the purchase or up to 6 months after the purchase.

Digital instructions - Specific

Due to the specificities of certain sector, we have **adapted** the digital instruction provision:

- For legislations dealing with products which are **not meant for consumers**, there is **no obligation to provide paper safety information**.
- For Regulation (EU) 2016/425, as there is **no 'safety information'** we have replaced it by the information listed in its Annex II. Moreover, for consumer products, instructions and information can be affixed **on the packaging**.



Coherent approach as regards the Digital Product Passport

An obligation to provide the information contained in the EU declaration of conformity and instructions on **the digital product passport** when the product is subject to other Union legislation that requires the use of such a digital product passport.

This will create **overall coherence** between the EU legislations and **avoid double administrative burden**.



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Any Questions ?



Common Specifications



Common specifications – Standards Policy

Simplification

🕒 COM(2025)30 - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - **A Competitiveness Compass for the EU**

📖 COM(2025)500 - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - **The Single Market: our European home market in an uncertain world**

💡 In situations where harmonised standards do not exist, are not available or there is an urgent need, we are proposing to align common specifications, as a fallback option, for companies to demonstrate compliance with EU rules.

Benefits

🛡️ Provide an alternative means for demonstrating conformity

⚖️ Increase legal predictability and certainty on compliance for businesses

💰 Reduce costs and regulatory complexity for businesses



Common specifications – Standards Policy

- **List of amended legislative acts**

- Recreational craft and personal watercraft - Directive 2013/53/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
- Low Voltage - Directive 2014/35/EU
- Radio equipment - Directive 2014/53/EU
- Pressure equipment - Directive 2014/68/EU
- Marine Equipment - Directive 2014/90/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Cableway installations - Regulation (EU) 2016/424
- Gas appliances - Regulation (EU) 2016/426
- Personal protective equipment - Regulation (EU) 2016/425
- Requirements for accreditation and market surveillance relating to the marketing of products - Regulation (EU) 2008/765



The importance of standards

- Standards are mentioned **100+ times** in the **Draghi report** and **70+** times in the **Letta report**.
- They are relevant for electricity grids, nuclear safety, critical raw materials, ICT, carbon emissions, public procurement, housing, mobility, international cooperation, space and defence.

“Common standards are essential to benefit from economies of scale and connectivity in the Single Market, and to create exemplary standards with global range.”

Draghi Report (2024, p. 154)



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.



Legal aspects

- Case C-588/21P: *Public.Resource.Org and Right to Know v Commission and Others*
Judgement of the European Court of Justice (Grand Chamber), *from 5 March 2024*.
The Grand chamber of the European Court of Justice ruled that the Commission erred in not disclosing access to four harmonised standards under the Access to Documents Regulation (EC) 1049/2001 and invoked the overriding public interest as prevailing over the copyright of a standard.
- Case- T-631/24: *International Electrotechnical Commission and ISO v Commission*
Action brought on 6 December 2024 by IEC and ISO
- Since March 2021, over 100 harmonised standards based on ISO/IEC standards were not delivered.



Adopted Common specifications

- 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



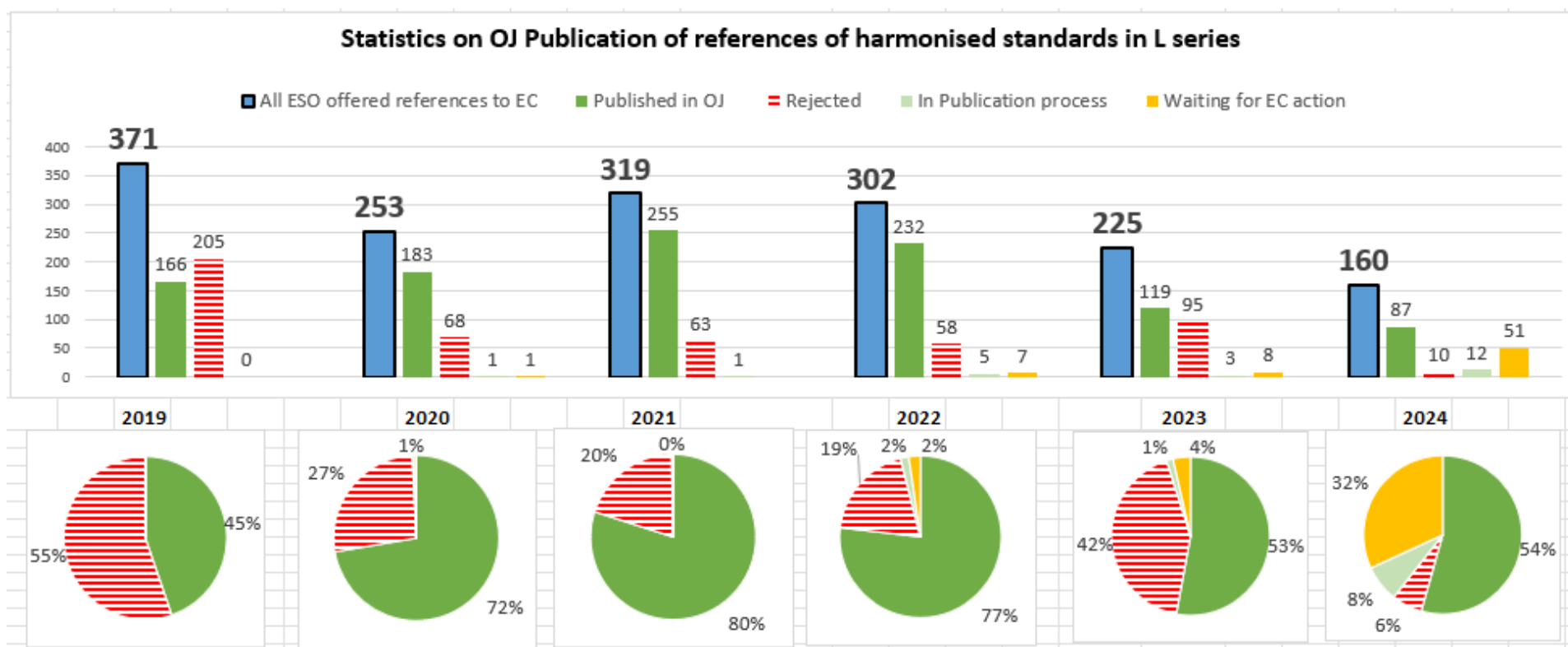
Average length to develop hENs

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

References received from ESOs 2019 ... Dec 2024



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Any Questions ?



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Thank you !



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