

HARMONISED STANDARDS & EMPIRICALLY INFORMED REGULATION: LESSONS FROM CYBERSECURITY

DR. IRENE KAMARA
TILBURG INSTITUTE FOR LAW, TECHNOLOGY, & SOCIETY

Tilburg Institute for Law, Technology, and Society/Tilburg Law School

Assistant Professor and Research coordinator

https://www.tilburguniversity.edu/staff/i-kamara

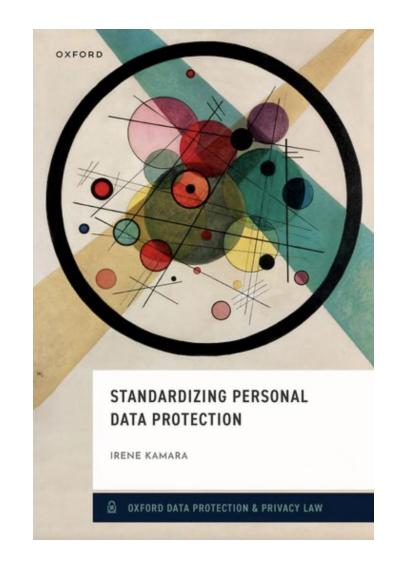
### **Specific standardisation activities:**

Invited member of NEN TC Cybersecurity & Privacy (2020-2024)

Studies for DG JUST, National Cybersecurity Centre NL, European Cybersecurity Agency ENISA on standards & certification

2021 CEN & CENELEC Standards & Innovation award: Individual researcher

CEN Workshop Agreement on evaluation criteria for security products and systems

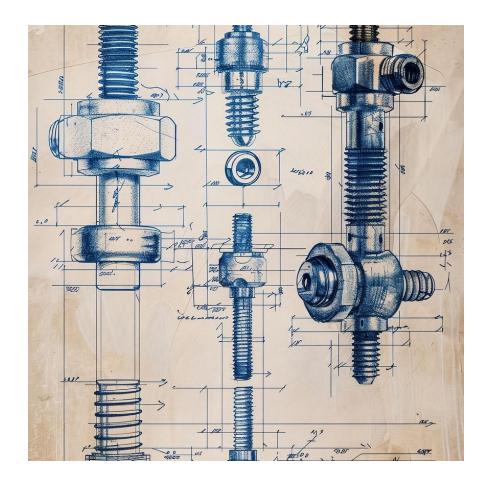


https://global.oup.com/academic/product/standardizing-personal-data-protection-9780198893288?cc=nl&lang=en&

# STRUCTURE

A. Why are we talking about standards?

- Importance of standards
- Definition and characteristics of a technical standard
- B. "Empirically informed"
  - -Who develops technical standards?
  - Which are the functions of standards [in relation to law]?
- C. Relation to (EU) public regulations
  - Are hENs (=harmonised european standards) part of the EU law?
  - -Oversight, representation, stakeholder participation
- D. What is next?



A. WHY ARE WE
TALKING ABOUT
TECHNICAL
STANDARDS?

# --> E U DIGITAL LAWS RECENTLY...



## Table 1: Overview of EU legislation in the digital sector



Research & Innovation	Industrial Policy	Connectivity	Data & Privacy	IPR	Cybersecurity	Law Enforcement	Trust & Safety	E-commerce & Consumer Protection	Competition & Single Market	Media	Finance
olgital Europe Programme legulation EU] 2021/694	Recovery and Resilience Facility Regulation (EU) 2021/241	Frequency Bands Directive (EEC) 1987/372	ePrivacy Directive (EC) 2002/58	Database Directive (EC) 1996/9	Regulation for a Cybersecurity Act (EU) 2019/881	Law Enforcement Directive (EU) 2016/680	Toys Regulation (EC) 2009/48, 2023/0290(COD)	Unfair Contract Terms Directive (UCTD) (EEC) 1993/13	EC Merger regulation (EC) 2004/139	Satellite and Cable Directive (EEC) 1993/83	Common VAT system (EC) 2006/112, 2022/0407(CNS), 2022/0409(CNS)
dorizon Europe legulation EU) 2021/695, (EU) 1021/764	InvestEU Programme Regulation (EU) 2021/523	Radio Spectrum Decision (EC) 2002/676	European Statistics (EC) 2009/223	Community Design Directive (EC) 2002/6	Regulation to establish a European Cybersecurity Competence Centre (EU) 2021/887	Directive on combating fraud and counterfeiting of non-cash means of payment (EU) 2019/713	European Standardization Regulation (EU) 2012/1025	Price Indication Directive (EC) 1998/6	Technology Transfer Block Exemption (EC) 2014/316	Information Society Directive (EC) 2001/29	Administrative cooperation in the fie taxation (EU) 2011/16
egulation on a pilot egime distributed ledger echnology EU) 2022/858	Connecting Europe Facility Regulation (EU) 2021/1153	Electromagnetic compatibility Directive (EMC) (EU) 2014/30	General Data Protection Regulation (GDPR) (EU) 2016/679	Enforcement Directive (IPR) (EC) 2004/48	NIS 2 Directive (EU) 2022/2555	Regulation on interoperability between EU information systems in the field of borders and visa (EU) 2019/817	Radio Equipment Directive (RED) (EU) 2014/53	E-commerce Directive (EC) 2000/31	Company Law Directive (EU) 2017/1132	Audio-visual Media Services Directive (AVMSD) (EU) 2010/13	Payment Service Dire 2 (PSD2) (EU) 2015/2366, 2023/0209(COD)
uropean Innovation Act	Regulation on High Performance Computing Joint Undertaking (EU) 2021/1173	Open Internet Access Regulation (EU) 2015/2120	Regulation to protect personal data processed by EU institutions, bodies, offices and agencies (EU) 2018/1725	Protection of trade secrets (Directive) (EU) 2016/943	Cybersecurity Regulation (EU) 2023/2841	Regulation on terrorist content online (EU) 2021/784	eIDAS Regulation (European Digital Identity Framework) (EU) 2014/910	Unfair Commercial Practices Directive (UCPD) (EC) 2005/29	Screening of foreign direct investments Regulation (EU) 2019/452	Portability Regulation (EU) 2017/1128	Digital Operational Resilience Act (DORA Regulation) (EU) 2022/2554
European Research Area Act	Regulation on Joint Undertakings under Horizon Europe (EU) 2021/2085	European Electronic Communications Code Directive (EECC) (EU) 2018/1972	Free flow of non-personal data (Regulation) (EU) 2018/1807	Design Directive (EU) 2024/2823	Cyber Resilience Act (EU) 2024/2847	Temporary CSAM Regulation (EU) 2021/1232, 2022/0155(COD)	Regulation for a Single Digital Gateway (EU) 2018/1724	Directive on Consumer Rights (CRD) (EU) 2011/83	Market Surveillance Regulation (EU) 2019/1020	Satellite and Cable II Directive (EU) 2019/789	Crypto-assets Regulat (MICA) (EU) 2023/1114
	Decision on a path to the Digital Decade (EU) 2022/2481	.eu top-level domain Regulation (EU) 2019/517	Open Data Directive (PSI) (EU) 2019/1024	Compulsory licensing of patents 2023/0129(COD)	Cyber Solidarity Act (Regulation) (EU) 2025/38	E-evidence Regulation (EU) 2023/1543	General Product Safety Regulation (EU) 2023/988	e-invoicing Directive (EU) 2014/55	P2B Regulation (EU) 2019/1150	Copyright Directive (EU) 2019/790	Anti-money launderin Regulation (AML) (EU) 2024/1624
	European Chips Act (Regulation) (EU) 2023/1781	Roaming Regulation (EU) 2022/612	Data Governance Act (Regulation) (EU) 2022/868		Information Security Regulation 2022/0084(COD)	Digitalisation of cross- border judicial cooperation (EU) 2023/2844	Machinery Regulation (EU) 2023/1230	Consumer Protection Cooperation Regulation (EU) 2017/2394	Single Market Programme (EU) 2021/690	European Media Freedom Act (EU) 2024/1083	Financial Data Access Regulation 2023/0205(COD)
	Establishing the Strategic Technologies for Europe Platform (STEP) (EU) 2024/795	Union Secure Connectivity Programme (EU) 2023/588	Data Act (Regulation) (EU) 2023/2854		Digital package	Directive on combating violence against women (EU) 2024/1385	Al Act (Regulation) (EU) 2024/1689	Geo-Blocking Regulation (EU) 2018/302	Vertical Block Exemption Regulation (VBER) (EU) 2022/720		Payment Services Regulation 2023/0210(COD)
	European Critical Raw Materials Act (Regulation) (EU) 2024/1252	Gigabit Infrastructure Act (EU) 2024/1309	Interoperable Europe Act (EU) 2024/903			Directive for combating sexual abuse and child sexual abuse material 2024/0035(COD)	Eco-design Regulation (EU) 2024/1781	Digital content Directive (EU) 2019/770	Digital Market Act (DMA Regulation) (EU) 2022/1925		Digital Euro 2023/0212(COD)
	Net Zero Industry Act (EU) 2024/1735	Digital Networks Act	Regulation on data collection for short-term rental (EU) 2024/1028			EU Digital Travel application, 2024/0670(COD)	Product Liability Directive (PLD) (EU) 2024/2853	Digital Contracts for Goods Directive (EU) 2019/771	Regulation on distortive foreign subsidies (EU) 2022/2560		Regulation on comba late payment 2023/0323(COD)
	EU Space Act	EU Cloud and Al Development Act	European Health Data Space (Regulation) (EU) 2025/327					Digital Services Act (DSA Regulation) (EU) 2022/2065	Horizontal Block Exemption Regulations (HBER) (EU) 2023/1066, (EU) 2023/1067		
	Quantum Act		Harmonization of GDPR enforcement procedures 2023/0202(COD)					Political Advertising Regulation (EU) 2024/900	Internal Market Emergency and Resilience Act (EU) 2024/2747		
	European Biotech Act		GreenData4all					Right to repair Directive (EU) 2024/1799	Platform Work Directive (PWD) (EU) 2024/2831		
	Advanced Materials Act		European Data Union Strategy					Digital Fairness Act	28th regime		
	Circular Economy Act								Revision of directives on Public Procurement		
Colour codi	ng:										
	hed in the I Journal of	In process Proposal by th Commission entered the legislative proc		Planned initiative Mentioned by the Commission as potential initiative							

https://www.ceps.eu/ceps-publications/a-dataset-of-international-legal-andpolicy-instruments-for-the-digital-world/

# DIGITAL LAWS & TECHNICAL STANDARDS

## NIS 2 Directive

#### Article 25

#### Standardisation

- 1. In order to promote the convergent implementation of Article 21(1) and (2), Member States shall, without imposing or discriminating in favour of the use of a particular type of technology, encourage the use of European and international standards and technical specifications relevant to the security of network and information systems.
- 2. ENISA, in cooperation with Member States, and, where appropriate, after consulting relevant stakeholders, shall draw up advice and guidelines regarding the technical areas to be considered in relation to paragraph 1 as well as regarding already existing standards, including national standards, which would allow for those areas to be covered.

## Cyber Resilience Act

#### Article 27

### Presumption of conformity

1. Products with digital elements and processes put in place by the manufacturer which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential cybersecurity requirements set out in Annex I covered by those standards or parts thereof.

The Commission shall, in accordance with Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential cybersecurity requirements set out in Annex I to this Regulation. When preparing standardisation requests for this Regulation, the Commission shall strive to take into account existing European and international standards for cybersecurity that are in place or under development in order to simplify the development of harmonised standards, in accordance with Regulation (EU) No 1025/2012.

### Al Act

### Article 40

### Harmonised standards and standardisation deliverables

1. High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this Regulation, to the extent that those standards cover those requirements or obligations.

### Data Act

#### Article 36

### Essential requirements regarding smart contracts for executing data sharing agreements

- 4. A smart contract that meets the harmonised standards or the relevant parts thereof, the references of which are published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements laid down in paragraph 1 to the extent that those requirements are covered by such harmonised standards or parts thereof.
- 5. The Commission shall, pursuant to Article 10 of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards that satisfy the essential requirements laid down in paragraph 1 of this Article.



### How the European Commission ensures transparency and accountability in the adoption of harmonised standards related to artificial intelligence in the context of the Al Act

Case opened

Case 1974/2025/MIK - Opened on 26/09/2025 - Institution concerned European

Commission |

https://www.ombudsman.europa.eu/en/case/en/69839

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# DEFINITION OF A TECHNICAL STANDARD

• Standard means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory.

(Art. 2(1) Regulation 1025/2012)

- →Specific bodies adopt standards
- → Voluntary compliance
  - → copyright protected & available for a fee
  - → No enforceability

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..standard' means a **technical specification**..

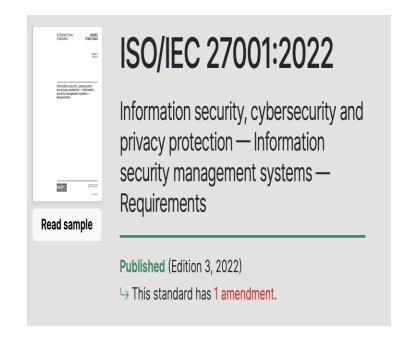
Technical specification is a document that prescribes technical requirements to be fulfilled by a product, process, service, or system

**characteristics** required of a product including levels of quality, performance, interoperability, environmental protection, health, safety or dimensions

production methods and processes used in agriculture

the **characteristics** required of a service including levels of quality, performance, interoperability, environmental protection, health or safety

the **methods and the criteria** for assessing the performance of construction products



# WHO DEVELOPS TECHNICAL STANDARDS

- Committee based standardisation
- 2. Market based standardisation
- 3. Co-development: standardisation bodies, with involvement of public regulator

### International



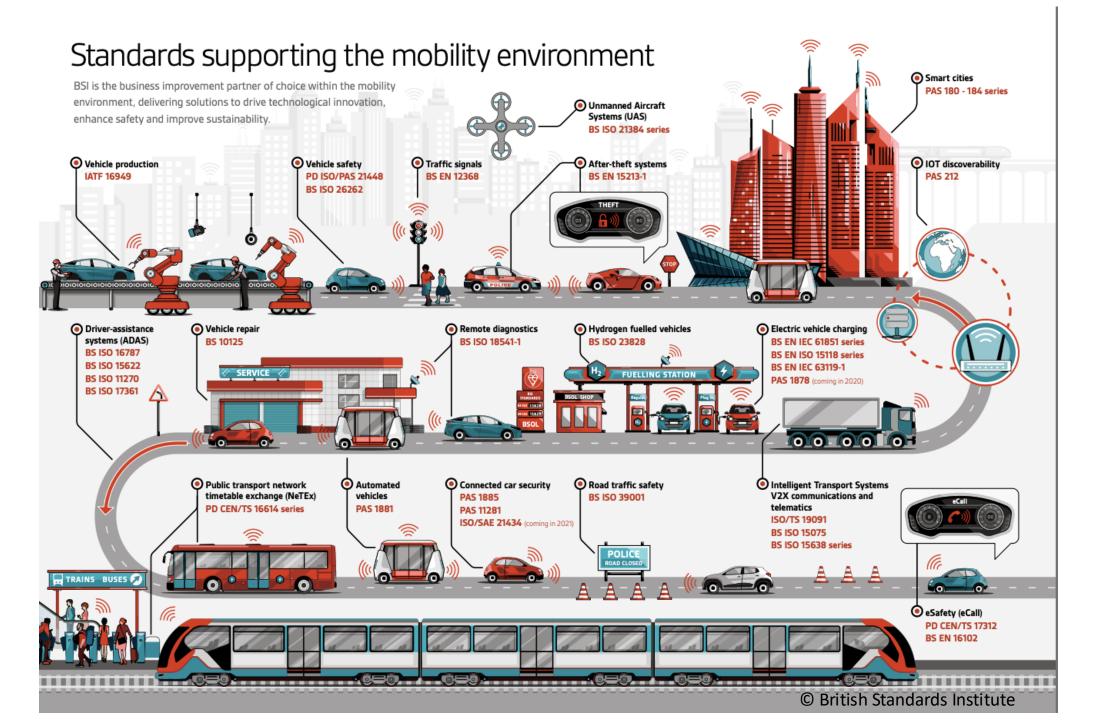






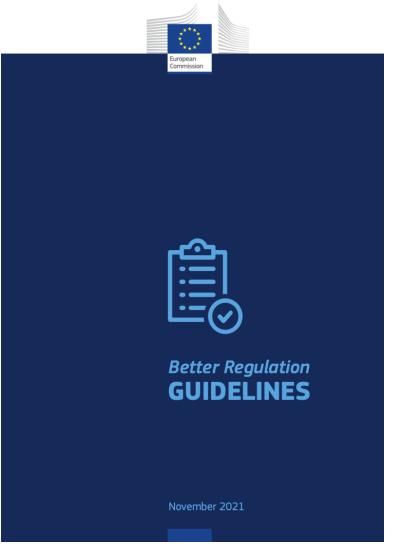
### **European Standardisation Organisations**

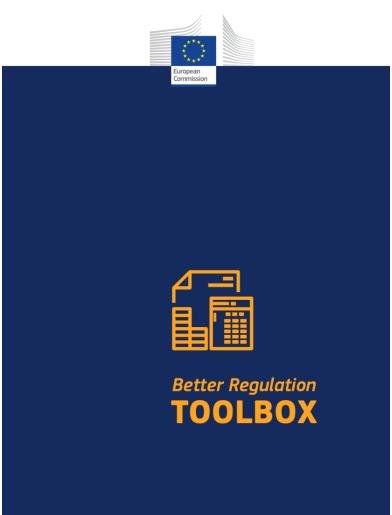




B. EMPIRICALLY
INFORMED
REGULATION &
STANDARDISATION

• "It is important to ensure that 'regulations have **strong empirical foundations**, both through careful analysis in advance and through retrospective review of what works and what does not" [Sunstein, 2011]





July 2023

Evidence-based and participatory policy making

JRC report (Listorti et al., 2020):

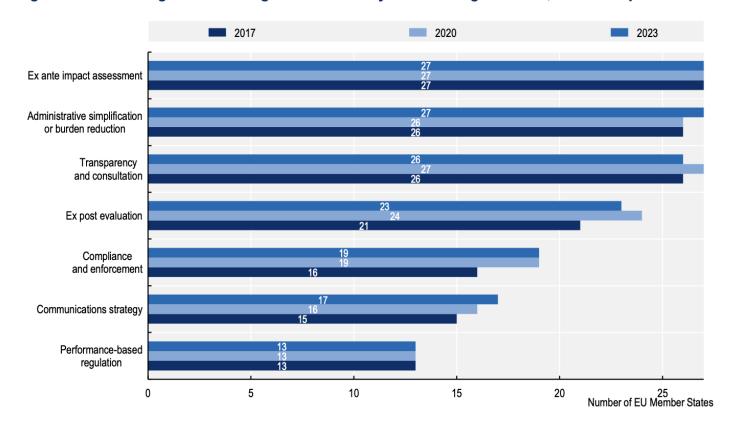
Several issues, including:

- Role of impact assessment to develop proposals is unclear
- Methodology issues & complexity to assess quality in ex post reviews

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Figure 1.1. Better regulation strategies focus mostly on the design of rules, less on implementation



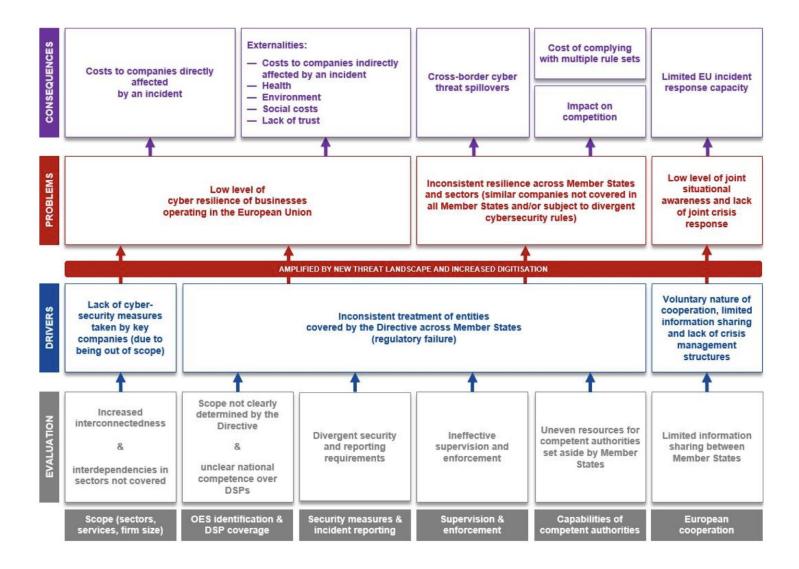
# Better Regulation Practices across the European Union 2025



Source: OECD Indicators of Regulatory Policy and Governance (iREG) 2024.

https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/09/better-regulation-practices-across-the-european-union-2025\_a3dfd5e6/6f007516-en.pdf

# OUTCOME OF NIS1 EVALUATION



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# "EMPIRICAL FOUNDATION ..."

- Types of knowledge that informs development/amendment/implementation of regulations [Head, 2008]:
  - political know-how
  - rigorous scientific and technical analysis
  - practical and professional field experience.

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# HOW DOES STANDARDISATION CONTRIBUTE EXPERT KNOWLEDGE?

# Clarity and interpretation

Definitions of concepts

Interpretation of principles

# Implementation and compliance

Uniform application of the law across sectors & Member States

Accountability fo those with a duty for legal compliance

Benchmark for supervisory authorities

# Technologyrelated

Translation of legal requirements to technical auditable requirements & controls

Enforcement by means of technology/ techno-regulation

State-of-the art, technical measures for compliance

The Role of Standards in Support of Technology Transfer." CEN CENELEC Guide 39, ed.1 March 2022.

'Keep up with leading technologies:

Standards provide information on leading industry technologies and practices, and are the basis of continuing education through testing, certification, and more. Participating in standardization activities allows you to keep abreast of market, technology, and policy changes—knowledge of which supports your entry to market and helps to enable interoperability.'

Stakeholder buy-in

The IEC and ISO's International Standards are developed in a multi-stakeholder environment which ensures that a wide range of technical views are represented, including those relating to social and economic interests The standards therefore already have the buy-in of a wide range of stakeholders, which can help guarantee a high level of acceptance for the policy guidance or legislation.'

ISO-IEC. 2015. "ISO and IEC International Standards for Policy Makers." Accessed June 15, 2023 Innovation: The European Journal of Social Science Research, 2024 Vol. 37, No. 5, 1441–1460, https://doi.org/10.1080/13511610.2024.2349626



## European cybersecurity standardisation: a tale of two solitudes in view of Europe's cyber resilience

Irene Kamara\*

Tilburg Institute for Law, Technology and Society, Tilburg Law School, Tilburg University, Tilburg, The Netherlands

(Received 4 August 2023; final version received 9 March 2024)

Cybersecurity resilience as a concept and EU policy approach encompasses, in broad terms, the preparedness of organisations against and the ability to recover from cyberattacks. Policy and law makers in the European Union have started endorsing strategies moving both towards reactive measures mitigating the consequences of cybersecurity incidents and proactive measures geared towards prevention. Recently, a political agreement was reached on a new horizontal Regulation addressing cyber resilience of products with digital elements. An essential aspect of the Cyber Resilience Act is technical standardisation to support its goals. How appropriate is however the European Standardisation system for such a role in EU cybersecurity law? The paper argues that for European standards to be conceptualised as a building block of cyber resilience in the European Union, their development process must be inclusive and open, and a prerequisite for that is that the ESOs jointly work towards the common goal of developing and adopting European standards in support of the EU cyber resilience policy and law. This collaborative approach is mandated both by the nature of cyber resilience and cybersecurity as regulated fields, but also the changing nature of standardisation aspiring to contribute to areas pertaining to societal interests and fundamental rights.

Keywords: CEN-CENELEC; cybersecurity; cyber resilience; CRA; empirically informed regulation; ETSI; standardisation



### And for whom?

(Regulated) entities

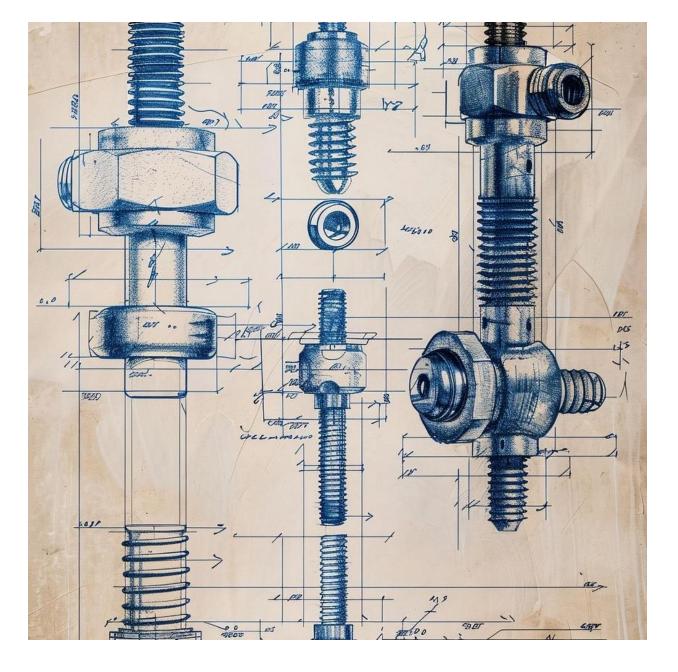
- e.g. manufacturers
- Al system providers

Beneficiaries

 Individuals impacted by non-compliance, e.g. consumers

Meta-rules (Parker, Binns)

 The working and implementation of the law itself.





# STANDARDS IN THE CYBER RESILIENCE ACT

- CHAPTER III
- CONFORMITY OF THE PRODUCT WITH DIGITAL ELEMENTS
   Article 27
- Presumption of conformity
- 1. Products with digital elements and processes put in place by the manufacturer which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the essential cybersecurity requirements set out in Annex I covered by those standards or parts thereof.
- The Commission shall, in accordance with Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential cybersecurity requirements set out in Annex I to this Regulation. When preparing standardisation requests for this Regulation, the Commission shall strive to take into account existing European and international standards for cybersecurity that are in place or under development in order to simplify the development of harmonised standards, in accordance with Regulation (EU) No 1025/2012.

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# THE EU STANDARDISATION MODEL: KEY INGREDIENTS

Three standardisation organisations, non-for profit, **not** EU agencies (CEN, CENELEC, ETSI)

When there is a need for a new standard + legal basis in EU (digital) law --> European Commission issues standardisation requests

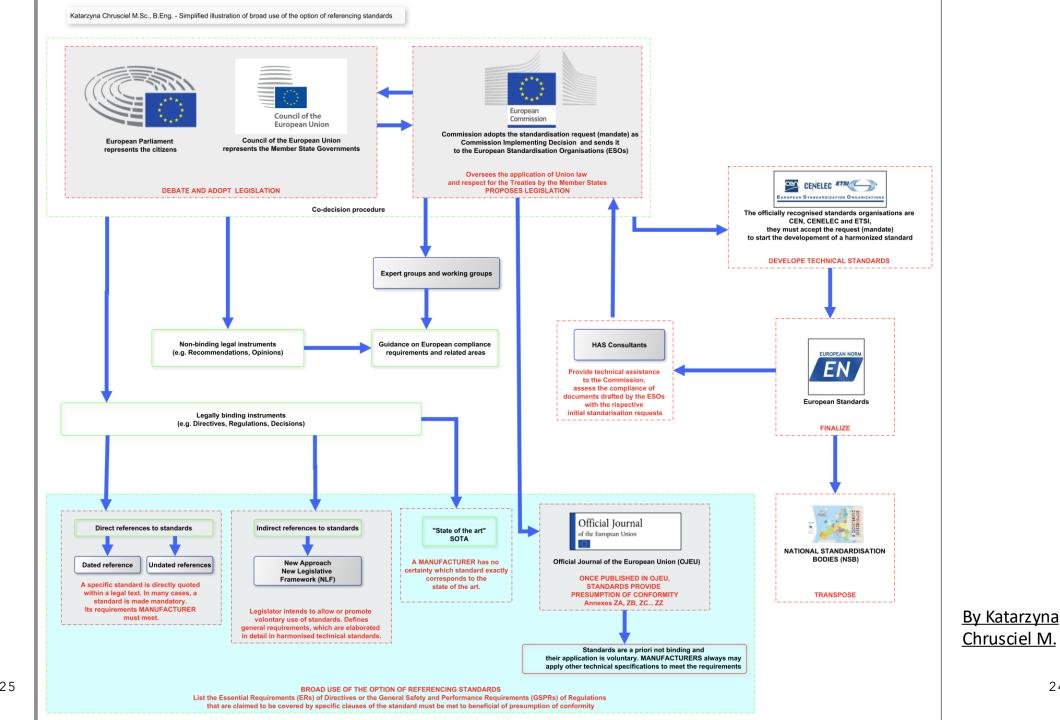
The ESOs may ACCEPT or REJECT the request

If all or some of them accept
--> Binding obligation

The Commission does NOT vote during the process.
Only observes.

After the draft European standard is adopted by ESOs --> Commission assesses its conformity with the standardisation request.

If it conforms --> the
Reference (not the full text)
is published in Official
Journal EU, status of
harmonised standard,
presumption of conformity



# Regulation 1025/2012

#### Article 10

### Standardisation requests to European standardisation organisations

### <u>▼M8</u>

1.

The Commission may, within the limitations of the competences laid down in the Treaties, request that one or more European standardisation organisations draft a European standard or European standardisation deliverable within a set deadline, provided that the European standardisation organisation concerned complies with paragraph 2a. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and be based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption.

### ▼B

2.

The decisions referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 22(3) after consultation of the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation as well as the committee set up by the corresponding Union legislation, when such a committee exists, or after other forms of consultation of sectoral experts.

### <u>▼M8</u>

2a.

Without prejudice to other advisory opinions, each European standardisation organisation shall ensure that the following decisions concerning European standards and European standardisation deliverables referred to in paragraph 1 are taken exclusively by representatives of the national standardisation bodies within the competent decision-making body of that organisation:

(a)

decisions on the acceptance and refusal of standardisation requests;

(b)

decisions on the acceptance of new work items that are needed for the fulfilment of the standardisation request; and

(c)

decisions on the adoption, revision and withdrawal of European standards or European standardisation deliverables.

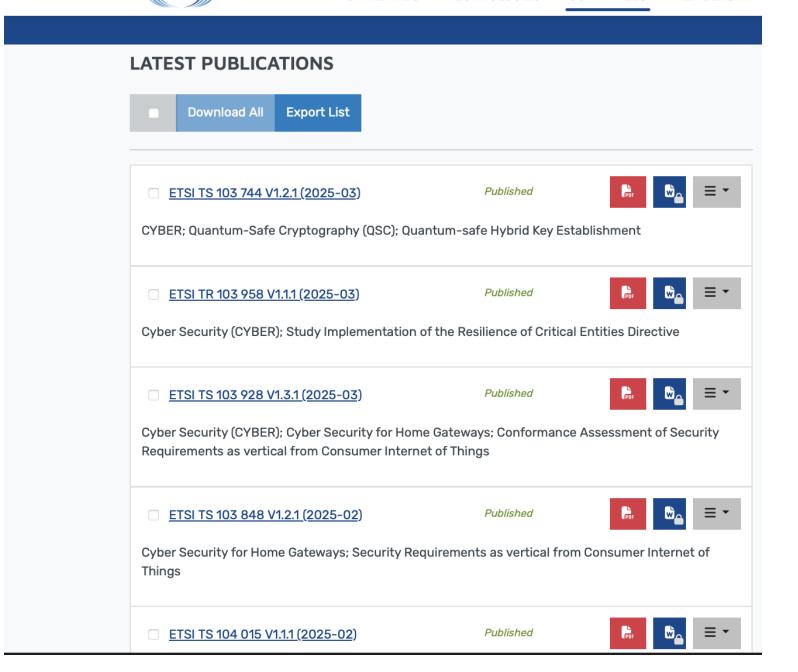
### CEN/CLC/JTC 13 Published Standards

A.
CEN/CLC/JT
C 13 Cybersecuri
ty and Data
Protection

Project reference, Title	Publication date	S
CEN ISO/IEC/TS 27006-2:2022 (WI=JT013049)  Requirements for bodies providing audit and certification of information security management systems - Part 2: Privacy information management systems (ISO/IEC TS 27006-2:2021)	2022-11-09	
CEN/CLC ISO/IEC/TS 23532-1:2024 (WI=JT013069) Information security, cybersecurity and privacy protection - Requirements for the competence of IT security testing and evaluation laboratories - Part 1: Evaluation for ISO/IEC 15408 (ISO/IEC/TS 23532-1:2021)	2024-09-25	
CEN/CLC ISO/IEC/TS 23532-2:2024 (WI=JT013070) Information security, cybersecurity and privacy protection - Requirements for the competence of IT security testing and evaluation laboratories - Part 2: Testing for ISO/IEC 19790 (ISO/IEC/TS 23532-2:2021)	2024-09-25	
CEN/CLC/TR 17919:2023 (WI=JT013026)  Data protection and privacy by design and by default - Technical Report on applicability to the video surveillance industry - State of the art	2023-02-01	
CEN/CLC/TS 17880:2022 (WI=JT013041) Protection Profile for Smart Meter - Minimum Security requirements	2022-12-21	
CEN/CLC/TS 18072:2025 (WI=JT013044) Requirements for Conformity Assessment Bodies certifying Cloud Services	2025-04-23	
CEN/TS 18026:2024 (WI=JT013043) Three-level approach for a set of cybersecurity requirements for cloud services	2024-04-24	:
EN 17529:2022 (WI=JT013025)  Data protection and privacy by design and by default	2022-05-18	

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# · B. ETSI TC CYber



### M/606 - C(2025)618

COMMISSION IMPLEMENTING DECISION of 3.2.2025 on a standardisation request to the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) as regards products with digital elements in support of Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act)

CEN CENELEC ETSI

Accepted the request

All requested harmonised European standards developed under this Decision shall be drafted in such a way that they may facilitate publication in the *Official Journal of the European Union*.

11/4/2025 28

# ARE STANDARDS REALLY VOLUNTARY?

- Standard means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory.
- (Art. 2(1) Regulation 1025/2012)

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# **CASE C-171/11** FRA.BO

- Copper fittings certification offered by a German certification body DVGW.
- FRA.bo, private company that applied for certification to DVGW and got their application initially accepted, and then re-assessed and rejected.
- DVGW were drafting their own 'standards' that they used for evaluating the products (copper fittings). Mid the process, the relevant standard --> amended, 3000 test.
- Before the rejection, FRA.bo had tried to pass the 3000 hour test, but with a lab that was not accredited by DVGW, but the latter did not accept the results from that lab.
- FRA.bo complained.

# FRA.BO II

• Arguments of FRA.bo

De facto mandatory

- Due to the presumption of compliance conferred on products certified by the DVGW it is virtually impossible for Fra.bo to distribute its products in Germany without that certificate.
- The 3 000-hour test has no objective justification
- the DVGW is not entitled to reject outright test reports from laboratories which are accredited by the competent authorities in Member States other than the Federal Republic of Germany

## Arguments of DVGW

- As a Private association -hence not bound by the provisions governing the free movement of goods principle
- nothing preventing the DVGW from drawing up technical standards which go beyond those in place in Member
   States other than the Federal Republic of Germany and to apply them to its certification activities.
- also free, on quality-related grounds, to take account only of laboratories accredited by it.

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# FRA.BO III: RULING

• DVGW is a non-profit, private-law body whose activities are not financed by the Federal Republic of Germany. Germany has "no decisive influence over the DVGW's standardisation and certification activities, although some of its members are public bodies."

### • BUT:

- According to german law, products certified by the DVGW are deemed compliant with national legislation [presumption of conformity]
- 2. DVGW was the only body able to certify the copper fittings at issue. While an alternative process via experts was allowed, there were no formal procedures estalbished and very costly --> little or no use
- the lack of certification by the DVGW places a considerable restriction on the marketing of the products concerned on the German market.

The DVGW, by virtue of its authority to certify the products, in reality holds the power to regulate the entry into the German market of products such as the copper fittings at issue in the main proceedings.

11/4/2025

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# STICHTING ROOKPREVENTIE

• CJEU Stichting Rookpreventie C-160/20 (measurement of emissions of tobacco filter cigarettes): mandatory reference to standards of the International Organization for Standardization (ISO) in EU legislation makes these standards binding on public, only if they been published in the OJ. [para 48.]

Binding
effect if
published in
Official
Journal EU

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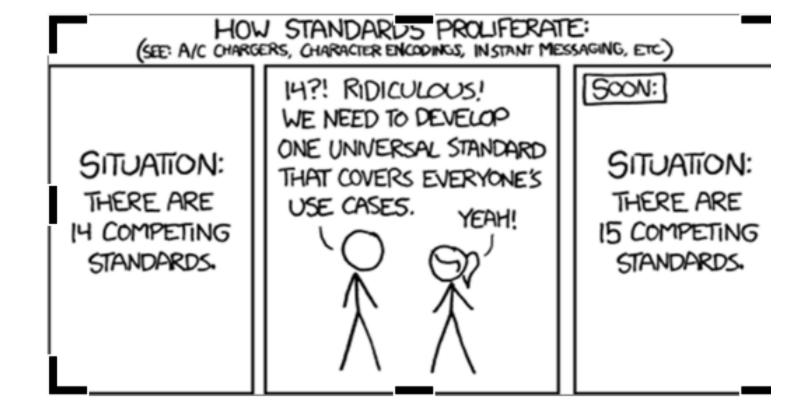
# FACTORS TO CONSIDER WHEN RELYING ON STANDARDS FOR EMPIRICALLY INFORMED REGULATION

- Juridification of standards [Schepel], without relevant safeguards,
  - no judicial review
  - no liability of standardisation organisations in case of a defective product relying on a problematic standard
  - Throughput Legitimacy issues: transparency of the process? Representation of all actors (see Ombudswoman complaint)?

# INTERPLAY - EUROPEAN V INTERNATIONAL STANDADS

- International standards such as from ISO and IEC are not developed with the regional legislations in mind
- Standards developers may be aware of legislation such as the CRA and even refer to it in an informative annex
- But aim is not to cover legal requirements of the CRA or other laws as such
  - > Consequence: not complete alignment
- Different terminology and scope
- Not all legal obligations are covered
- Standards have limited scope and application area

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## THREE IMPORTANT COURT CASES

- CJEU James Elliott C-613/14 (sulphur levels included in construction product above the harmonised standard --> caused damage in flooring of building, infringement of contract among private parties): harmonised standards form part of EU law due to their legal effects.
- Does the CJEU have jurisdiction? Yes.
  - "a harmonised standard such as that at issue in the main proceedings, adopted on the basis of Directive 89/106 and the references to which have been published in the Official Journal of the European Union, forms part of EU law, since it is by reference to the provisions of such a standard that it is established whether or not the presumption laid down in Article 4(2) of Directive 89/106 applies to a given product."
  - "while the development of such a harmonised standard is indeed entrusted to an organisation governed by private law, it is nevertheless a necessary implementation measure which is strictly governed by the essential requirements defined by that directive, initiated, managed and monitored by the Commission, and its legal effects are subject to prior publication by the Commission of its references in the 'C' series of the Official Journal of the European Union"
- Is the hEN binding for national courts for private disputes? No.
- harmonised standard EN 13242:2002 must be interpreted as not binding a national court seised of a dispute
  concerning a contract governed by private law requiring a party to supply a product compliant with a national
  standard transposing that harmonised standard, either as regards the method of establishing the conformity of
  such a construction product with the contractual specifications or the time at which its conformity must be
  established. [para 53]

Harmonised standards are "part of EU law"

11/4/2025

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# PUBLIC.RESOURCE.ORG (MALAMUD

## CASE)

- T-185/19 Public.Resource.Org and Right to Know v Commission [General Court]
- Appeal: CJEU case Case C-588/21 P
- Request to the European Commission Regulation No 1049/2001 and Regulation
  No 1367/2006, for access to documents held
  by the Commission ('the request for access').
  - 4 harmonised European standards based on standardisation requests - toy safety
- COM refused the request, application to General Court asked for annulment of COM decision.
- GC rejected the pleas and dismissed the action.

- Art. 2 1049/2001
- 1. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions, subject to the principles, conditions and limits defined in this Regulation.
- Art. 4(2) 1049/2001 exception
- 2. The institutions shall refuse access to a document where disclosure would undermine the protection of:
- commercial interests of a natural or legal person, including intellectual property,
- court proceedings and legal advice,
- the purpose of inspections, investigations and audits,

unless there is an overriding public interest in disclosure.

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Appelants "by virtue of the principle of the rule of law, which requires free access to EU law, an
overriding public interest justifying access to those standards for all natural or legal persons residing
or having their registered office in a Member State, on the ground that those rules form part of EU
law." [para65]

#### CJEU

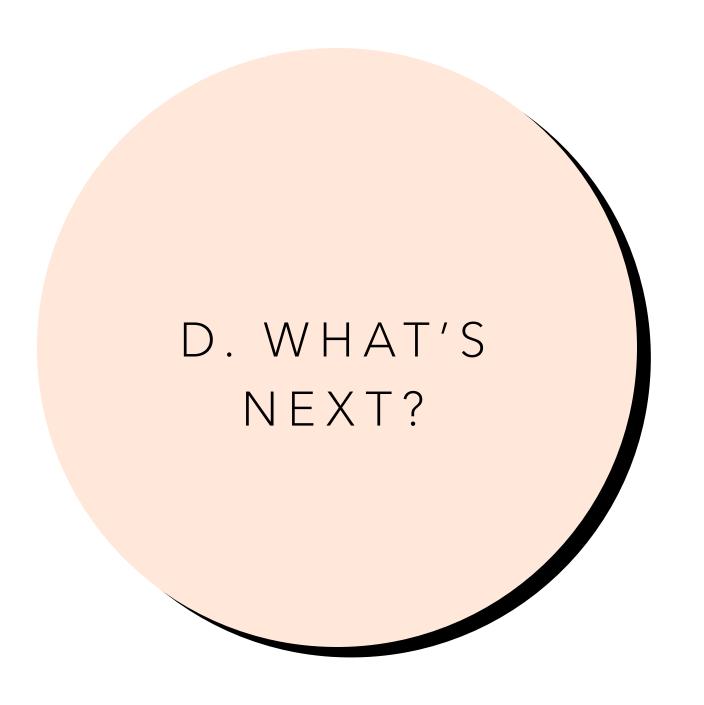
- Access to documents is a fundamental right (art. 42 CFREU)
- Standards are part of EU law and may be binding when published in OJ.
- The Commission plays a central role in the European standardisation system: requests the standardisation body, defines the requirements for the content, deadline for adoption, process supervised by COM, financed by COM.
- Presumption of conformity to challenge it, access to standards is required. Toys have been manuufactured based on the requested standards.
- While compliance with standards is not generally mandatory, harmonised standards in question are 'manifestly' mandatory [para 79]
- Is there overriding public interest?
  - Transparency and openness principles make it possible, inter alia, to ensure that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system [para 83] -> an overriding public interest of disclosing the standards in question exists.

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## CONSEQUENCE

 Commission decision of 27 September 2024 to grant access to standards in response to requests made under Regulation (EC) 1049/2001



# A. ISO & IEC: CASE T-631/24

- General Court case pending
- Action by ISO and IEC → Annulment of the Commission's decision of 27 September 2024 to grant access to International Standards belonging to IEC and ISO, in response to requests made under Regulation (EC) 1049/2001
- a. errors of assessment and lack of reasoning in the application of Article 4 of Regulation (EC) No 1049/2001
- b. infringement of the Treaties or any rule of law relating to their application
- c. infringement of essential procedural requirements

There is no overriding public interest within the meaning of Article 4(2) of Regulation (EC) 1049/2001 in favour of the disclosure of IEC and ISO International Standards, which will seriously undermine the commercial interests and the valuable intellectual property of IEC and ISO. The Commission should refuse, and should have refused, Access Requests relating to the disclosure of IEC and ISO International Standards

COM failed to provide fair compensation in good time under Article 17 of the Charter in return for ISO & IEC deprivation of the applicants' intellectual property

COM failed to consult with ISO & IEC as third parties with a view to assessing whether the exceptions in Article 4(1) or 4(2)

## Toy safety

### Directive 2009/48/EC

Short name Toy safety

Base Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the

safety of toys

OJ L 170, 30 June 2009

[-] Modification

Directives repealed Council Directive 88/378/EEC for 3 May 1988 on the approximation of the laws of the Member

States concerning the safety of toys

OJ L 187 of 6 July 1988

Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20

2013.

July 2011. Article 2(1) thereof and Part 3 of Anr Summary list of titles and references of harmonised standards under Directive 2009/48/EC for Toys

The summary below consolidates the references of harmonised standards published by the Commission in the Official Journal of the European Union (OJ). It reproduces information already published in the L or C series of the OJ. It contains all references which, when the summary was generated, still provided a presumption of conformity together with references already withdrawn from the OJ.

The Commission services provide this summary for information purposes only. Although they take every possible precaution to ensure that the summary is updated regularly and is correct, errors may occur and the summary may not be complete at a certain point in time. The summary does not as such generate legal effects.

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#### Created on 12.9.2025

		Reference and title Provision	Start of	Publication	Publication Decision			Withdrawal OJ	Withdrawal Decision	
		EN 62115:2005								
		Electric toys - Safety#IEC 62115:2003								
		(Modified) + A1:2004								
2009/48/EC - Safety		EN 62115:2005/A2:2011								
of Toys	Cenelec	EN 62115:2005/A2:2011/AC:2011	11.08.2011	OJ C 235		11.08.2011	15.11.2012	OJ C 349		15.11.2012
		EN 62115:2005								
		Electric toys - Safety#IEC 62115:2003								
		(Modified) + A1:2004								
		EN 62115:2005/A2:2011								
		EN 62115:2005/A2:2011/AC:2011								
2009/48/EC - Safety		EN 62115:2005/A11:2012								
of Toys	Cenelec	EN 62115:2005/A11:2012/AC:2013	15.11.2012	OJ C 349		15.11.2012	03.06.2017	OJ C 196		12.06.2015
		EN 62115:2005								
		Electric toys - Safety#IEC 62115:2003								
		(Modified) + A1:2004								
		EN 62115:2005/A2:2011								
		EN 62115:2005/A2:2011/AC:2011								
		EN 62115:2005/A11:2012								
2009/48/EC - Safety		EN 62115:2005/A11:2012/AC:2013								
of Toys	Cenelec	EN 62115:2005/A12:2015	12.06.2015	OJ C 196		12.06.2015	21.02.2022	OJ L 190	2021/867	31.05.2021
		EN 71-1:2011								
		Safety of toys - Part 1: Mechanical and								
009/48/EC - Safety		physical properties								
f Toys	CEN		18.06.2011	OJ C 178		18.06.2011	30.09.2014	OJ C 317		31.10.2013
		EN 71-1:2011+A2:2013								
		Safety of toys - Part 1: Mechanical and								
009/48/EC - Safety		physical properties								
of Toys	CEN		31.10.2013	OJ C 317		31.10.2013	30.09.2014	OJ C 181		13.06.2014
		EN 71-1:2011+A3:2014								
		Safety of toys - Part 1: Mechanical and								
009/48/EC - Safety		physical properties								
f Toys	CEN	50 St St St	13.06.2014	OJ C 181		13.06.2014	29.02.2016	OJ C 87		13.03.2015
		EN 71-1:2014								

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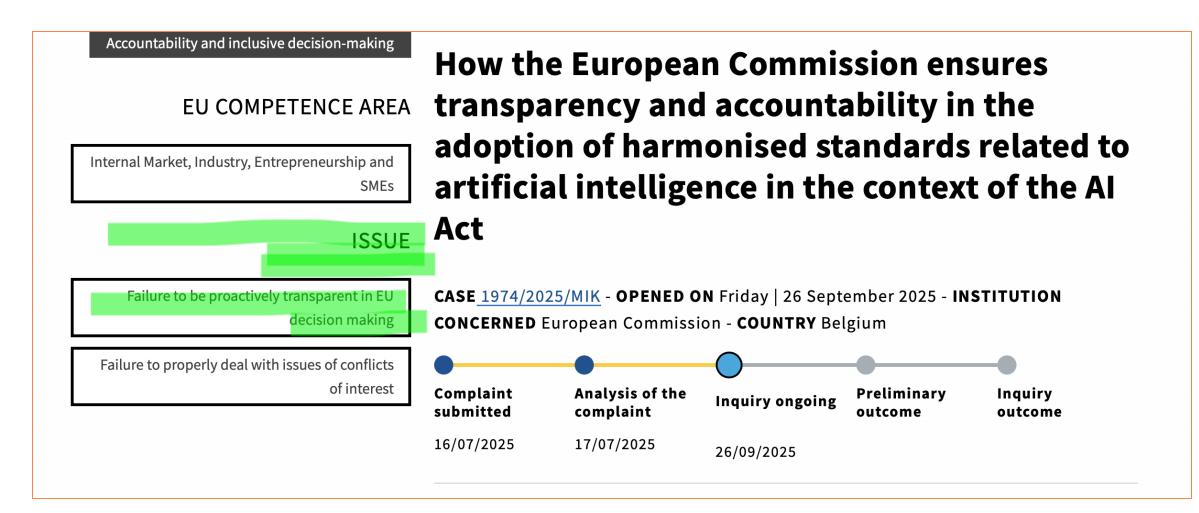
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## B. OMBUDSWOMAN CASE



## OMBUDSWOMAN CASE 1974/2025/MIK

- Concerns the AI Act standardization request but is relevant to all digital laws standardization requests, incl. the CRA request.
- QUESTIONS to the COMMISSION
- A. The Commission's role in reviewing the process of developing harmonised standards on AI and its outcomes
- B. The transparency of the process: confidentiality rules & transparency processes
- C. Inclusiveness of standardization process
  - Next to Annex III organisations

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# OMBUDSWOMAN CASE II: REQUESTED DOCUMENTS

- · the results of any interim reviews of the draft harmonised standards produced by CEN and
- CENELEC and any documents relating to these reviews,
- - transparency and confidentiality rules or policies applicable to the work of CEN and CENELEC
- on the harmonised standards on AI,
- - a list of the names and affiliations (companies, authorities, organisations etc.) of the members
- of JTC 21,
- a list of the names and affiliations of the members of the task force on inclusivity,
- - a list of meetings of the task force on inclusivity, including any agendas, minutes or reports
- - outcomes of the meetings of the task force on inclusivity, including any decisions taken.

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# C. REVISION OF REGULATION 1025/2012

- Consultation open for the proposal for a revision of 1025/2012 27 September to 17
   December
- <a href="https://single-market-economy.ec.europa.eu/consultations/public-consultation-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation\_en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation\_en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation\_en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-regulation-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-eu-no-10252012-also-called-eu-standardisation-en-proposal-revision-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-standardisation-eu-no-10252012-also-called-eu-no-10252012-also-
- The focus of the consultation is specifically on standards developed to support EU law or policies, including harmonised standards (rather than other industry standards).

## REVISION OF REGULATION 1025/2012

- Speed and responsiveness to innovation
- "The results of the evaluation of the Standardisation Regulation highlight slow, complex processes, delays due to lengthy quality assessments, limited digitisation, and insufficient flexibility in finding alternatives when (harmonised) standards are not available in a timely manner. The Commission aims to make the standardisation process faster and more flexible."
  - "When using standards from recognised international standardisation bodies such as ISO, IEC and ITU, there should be a faster adaptation, adoption and take-up in the EU system."
  - Expand the list of European Standardisation Organisations.

- Inclusiveness of the standardisation process
- "Regarding achieving a balanced stakeholder participation in standardisation work, several barriers remain, in particular the lack of financial support and incentives for EU SMEs, startups, civil society and academia. Some organisations may lack the awareness, skills and resources to participate effectively, and are therefore underrepresented in the standardisation process. This is particularly acute in complex technical domains where working with standards requires scarce specialist knowledge."
  - Voting rights for SMEs, consumers and other societal stakeholders (Annex III) in the standardisation process.
  - An obligation on ESOs and NSBs to ensure a minimum share of specific stakeholder interest in standardization.

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### Access to standards

- "Ensuring accessibility especially for citizens, public authorities and SMEs is therefore a matter of legal compliance and fair competition."
  - The legally relevant content of standards should be published and freely accessible by default.
  - Free access to a simplified summary of a standard's content would be useful.

### EU's role in global standard-setting

- build structural alliances with like-minded partners at the international level to amplify its values and strategic goals
- What aspects should be evaluated when considering the legislative use of international standards at EU level?

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## KEY TAKEAWAYS

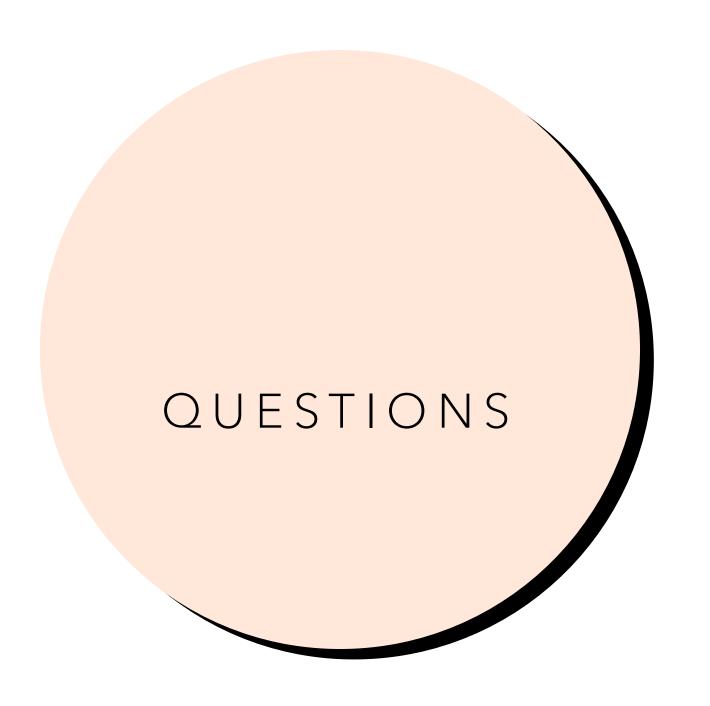
- Standards and their development frame, guide, and harmonise almost all areas of our lives.
- Standards allow technology to work seamlessly and establish trust so that markets can operate smoothly:
- provide a common language to measure and evaluate performance,
- make interoperability of components made by different companies possible, and Provide essential requirements e,g.to ensure safety, cybersecurity.

- → Good practices, expertise and knowledge
   → Cybersecurity has been benefitting from information security standards for many décades - this is now formalised through references to standardisation in key EÚ Cybersec laws
- Standards are a market instrument, developed by and for the market players

## KEY TAKEAWAYS II

- When used in policy/law context → cautiousness
- Technical expertise and 'good practices' are far from neutral contributions
- Quality should be thoroughly reviewed
- Participation and interest representation
- Evolving field: regulatory and case law developments, harmonised standards under development

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## ADDITIONAL INFORMATION

- EURAS annual conference: <a href="https://www.euras.org/">https://www.euras.org/</a>
- Journal of standardisation: <a href="https://journals.open.tudelft.nl/jos">https://journals.open.tudelft.nl/jos</a>
- EDU4Standards project website: <a href="https://edu4standards.eu">https://edu4standards.eu</a>



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