

The Role of European Standardization for AI - Harmonized Standards: Status, Timeline, and Challenges

Standard Norway – Building a trusted future seminar

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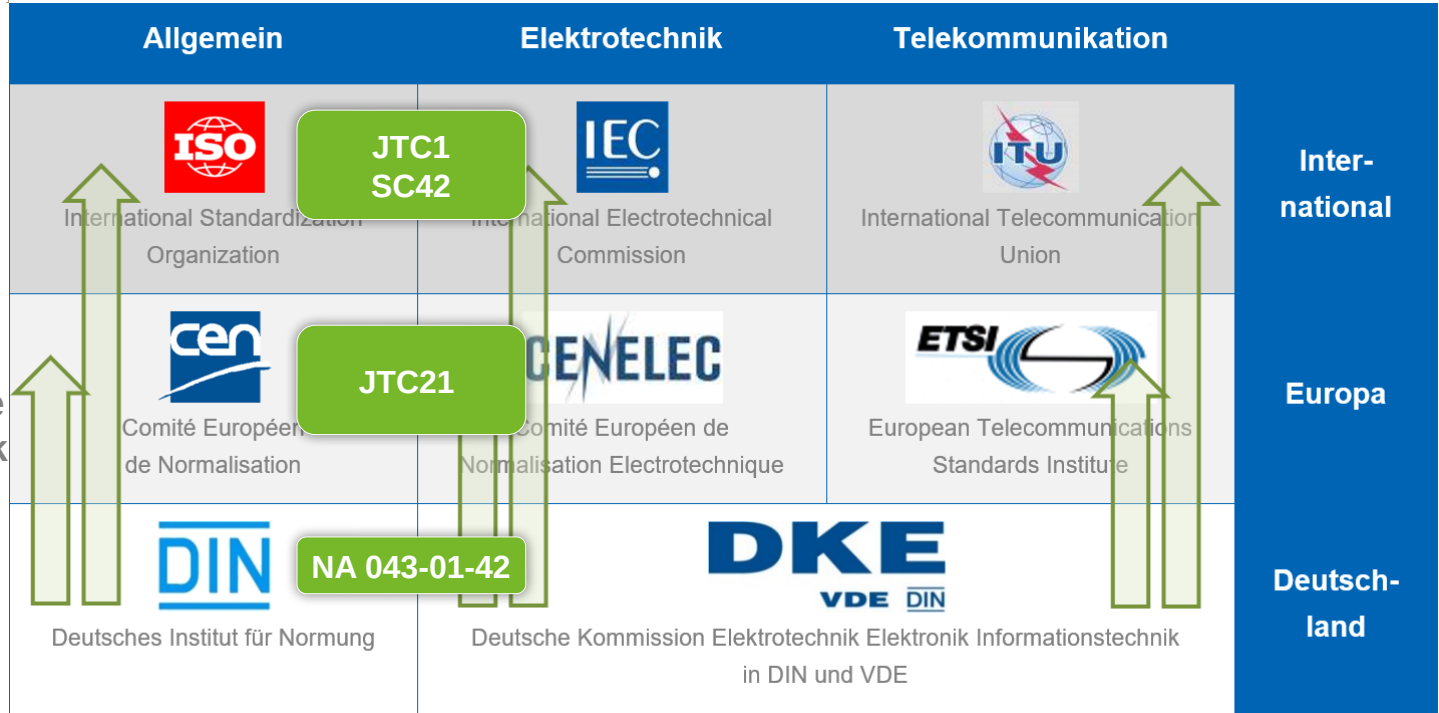


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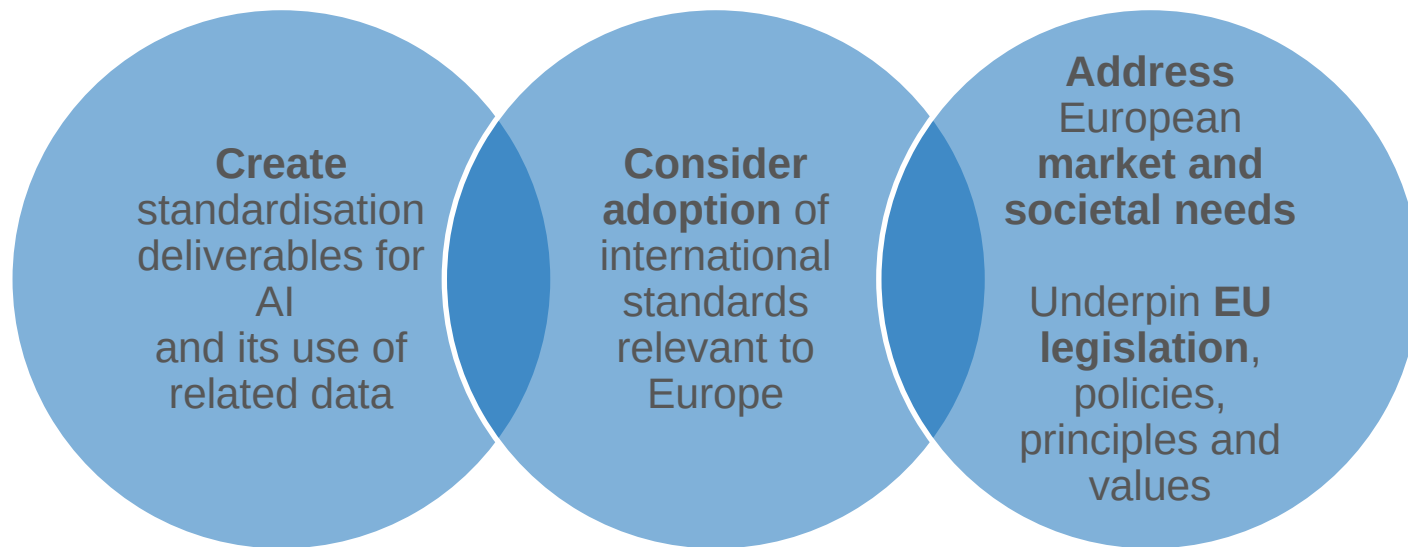


Global three-tier standardisation landscape

New
Legislative
Framework



Mission of JTC21



New Legislative Framework - Principles and structure

(as presented by the European Commission)



- ▶ **Essential requirements** designed to ensure a high-level of protection of public interests. They define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so
- ▶ **Harmonized standards** detailing technical solutions to meet the essential requirements
 - ▶ Voluntary – manufacturers can use other methods
 - ▶ Presumption of conformity with the essential requirements they cover
- ▶ **Division of responsibilities** along the value & distribution chain of the product
 - ▶ Manufacturers, importers, distributors, authorized representatives
- ▶ **Conformity assessment procedures**
 - ▶ Internal checks
 - ▶ Third-party assessment

Standardisation request of the European Commission

1.	European standard(s) and/or European standardisation deliverable(s) on risk management system for AI systems
2.	European standard(s) and/or European standardisation deliverable(s) on governance and quality of datasets used to build AI systems
3.	European standard(s) and/or European standardisation deliverable(s) on record keeping through logging capabilities by AI systems
4.	European standard(s) and/or European standardisation deliverable(s) on transparency and information provisions to the users of AI systems
5.	European standard(s) and/or European standardisation deliverable(s) on human oversight of AI systems

6.	European standard(s) and/or European standardisation deliverable(s) on accuracy specifications for AI systems
7.	European standard(s) and/or European standardisation deliverable(s) on robustness specifications for AI systems
8.	European standard(s) and/or European standardisation deliverable(s) on cybersecurity specifications for AI systems
9.	European standard(s) and/or European standardisation deliverable(s) on quality management system for providers of AI systems, including post-market monitoring process
10.	European standard(s) and/or European standardisation deliverable(s) on conformity assessment for AI systems

[illegible]

On ISO/IEC 42001: Management System Standard for AI

- Published November 2023; global wave of consulting and testing offerings
- **Why not just adopt 42001 for Europe?**
- Clear and early „no“ from the EU due to multiple mismatch:

42001	Bedarf für AI Act
Understanding of risk from ISO 31000 / Guide 73: risk = uncertainty	Understanding of risk from IEC Guide 51: risk = harm x probability of harm
Refers to an organisation	Refers to a product
Focus on Good Practice	Focus on measureable, enforceable requirements



Approach in JTC21:

EU-specific standards for quality and risk management but with references to ISO/IEC 42001 and other standards.

JT021011	prEN ISO/IEC 42001		WG2	Marta Janczarski	Information technology - Artificial intelligence - Management system	Adoption of 42001	Preliminary
JT021039	prEN XXX	EN	WG2	Adam Leon Smith	AI - quality management system for regulatory purposes	Complements, and builds on, several ISO/IEC standards, including 42001	Under Drafting

Working Groups

- WG1: Strategic Advisory Group
- WG2: Operational Aspects
- WG3: Engineering Aspects
- WG4: Foundational and Societal Aspects
- WG5: Cybersecurity
(in collaboration with ETSI, ENISA and CEN-CENELEC JTC13)

~200 experts directly in JTC21
~25 countries
>1000 experts at national level



How stakeholders participate in JTC21

- Through national AI mirror committees

- Through Annex 3 organisations



- Indirectly through liaisons
including other technical committees, associations, networks etc.

- Through ETSI
Mode 4 cooperation in place, including (but not limited to) cybersecurity

Challenges in (AI) standardisation as an almost integral part of regulation (I)

- **Legitimacy**

- Theory:

- Consensus of „all relevant stakeholders“
including companies of all sizes, academia, civil society,
broad spectrum of countries, whole AI lifecycle, ...

- Practice:

- Who has got time, technical specialists and process knowledge?
Documents vs. people

- **Very divergent interests**

- Global companies shape European standards

- Specific European perspectives and interests; sovereignty

- Differences between national mirror committees

Challenges in (AI) standardisation as an almost integral part of regulation (II)

- **Policy making vs. standardisation**
Need to respect outcome of political processes.
- **International standards designed for a different purpose**
Differences in testability, enforcability, links to regulation
- **Tight collaboration of broad spectrum of talents needed**
People with **technical** expertise in AI
People with **process** expertise in standardisation
People with **domain** expertise (health, energy, ...)
People who **can write** (!)
People who **can build consensus** (!!)

Timeline

- CEN-CENELEC: AI Focus Group since **2019** | JTC21 since **2021**
- AI Act **final**: August 2024
- Stocktaking review by COM / AI Office **Feb 2025**
=> shared understanding of remaining gaps
- Public consultation for drafts of harmonised standards („**Enquiry Vote**“) mostly from **Q3 / 2025**
- Integration of feedback („**Comment Resolution**“) mostly in **Q4 / 2025** and early 2026 => mature content
- Implementation deadline high-risk requirements **Aug 2026**
- Formal processes in CEN-CENELEC and COM / AI Office for finalisation, harmonisation and OJEU publication

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graph TD; A["Identify AI applications across the organisation
Map to risk categories, esp. high-risk"] --> B["Scope the implementation project(s) for AI Act compliance; plan/allocate resources"]; B --> C["Execute the implementation project(s)
=> AI Act compliance via harmonised standards"]
```
- Identify AI applications across the organisation
  - Map to risk categories, esp. high-risk

- Scope the implementation project(s) for AI Act compliance; plan/allocate resources

- Execute the implementation project(s)
- => AI Act compliance via harmonised standards

# JTC21 standards are currently distinct from the Code of Practice

|                                        | JTC21 harmonised standards                                                                                                                                                                                                                                                                                                                                                   | Code of Practice                                                                                                                                                                                                                                    |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Providing implementation steps for ... | Requirements on AI systems in high-risk applications – Articles 8 to 15 <ul style="list-style-type: none"><li>• <b>All</b> types of AI</li><li>• <b>Late</b> stage of value chain</li></ul>                                                                                                                                                                                  | Requirements on General Purpose Models – Articles 53, 55 <ul style="list-style-type: none"><li>• Generative AI <b>only</b></li><li>• <b>Early</b> stage of value chain</li></ul>                                                                    |
| Development context and process        | <ul style="list-style-type: none"><li>• Broadly applicable complex set of CEN-CENELEC regulations</li><li>• Decision making power with standardisation bodies at national level who also provide secretarial support (~25 countries)</li><li>• Input from ISO/IEC (under Vienna/Frankfurt agreements)</li><li>• Ongoing feedback/guidance from EC at working level</li></ul> | <ul style="list-style-type: none"><li>• Custom process and structure created for CoP development purposes</li><li>• Process directed by AI Office with outsourced facilitation support</li><li>• Decision making power with the AI Office</li></ul> |

**Potentially initiation of a standardisation request based on the CoP**