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

OECD. AI
Policy Observatory

Standard Norway – Building a trusted future seminar

#### Dr Sebastian Hallensleben



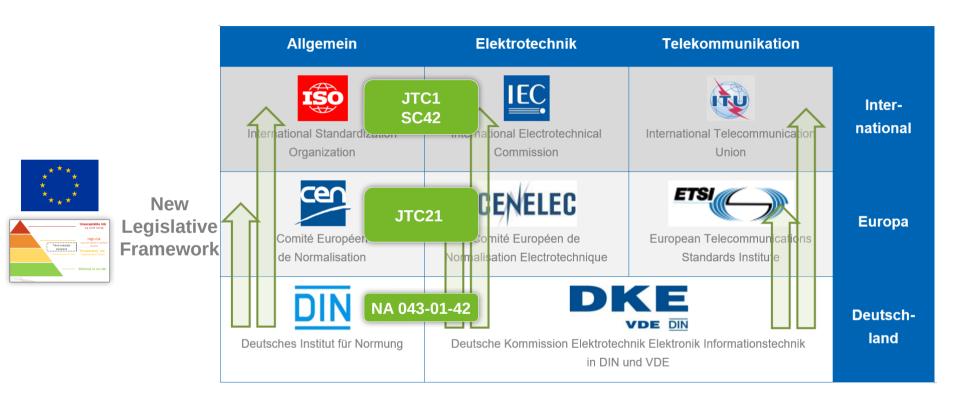
Chair CEN-CENELEC JTC21
Chief Trust Officer, Resaro
Co-Chair AI Risk & Accountability OECD ONE.AI
Programme Chair, Digital Trust Convention
Principal Advisor Digital Trust, KI Park





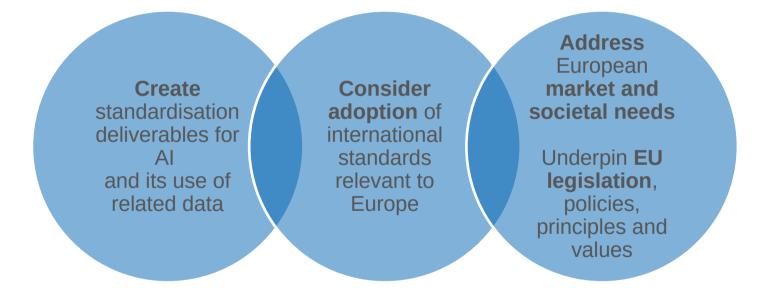
2025-05-14

## Global three-tier standardisation landscape



### **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 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

www.linkedin.com/in/sebastianhallensleben

sebastian@haller

This deathbased above the search there are all the search there is a search the search the search of	CON-CONECTOR or of Region SCA.  The Control of Scan Scan Scan Scan Scan Scan Scan Scan	construction of the second sec		Requirements and makes and to the dead formation and the state of the dead formation and the state of the sta	_	Paper that marked FECS - insurance independent allowed, smalls, in FECS - Insurance independent or the discussion of independent and insurance discussion and productions and as not require trade insurance.	Design to the second se		Company of the control of the contro	Market and the second of the s	and PROJECTS the of Schools of Schools and a product of a	consideration by with Young count, of become to gribe 100.		the strendings benty" artistical title temporals
	711	**************************************	To age of the last	The form of the second particle of the second form	*****	Edition of the Control of the Contro	Georgia (* 18	17 Same In 17	Contraction of the Contraction o	south py so	finish di Apang Analysis di Apang	a woonpook is	u spogodkije	Times present present bit
A A A 2 - A		cooling Darley of the	E STATE OF THE STA					~			-		_	
**************************************		Higher of 22484	P.11.111	mental in the second		Birelost printer = 2822. Billos Mr Mr [18M, Coreses]								
27 331 188218C BE ME4	Information for International Community Commun		attalia.					Н	$\top$	+	+	+	$\vdash$	
******	Ministration of the State of S	Eligina (1.33883	F-1-1-1	<b>EE</b> printer		#1.=1  j.1.1.1.1 = 3#33. #11 W.= F.1.  W #5.]	:	$\Box$	_		_	+	H	=
1, ME3	***************************************	P 1 1		- MEI		E=11 = ME3			_			$\pm$		
1 // 2.10   100 / 100   MC3 // 100   MC3		Higher of 42881 in, come 1887185 idealists, and as		1 18Y		Minetest potates		$\vdash$	+	+	+	+	Н	
15 15 15 15 MES		Bloglow of 22844	F-1-1-1	Equation and the 77 Sales of particles Should		Blocked policiel	_	·	#			$\pm$		_
31 1885/8E 88 MES 1118	** =	F 1, 1881	#=1:- #=1:-	In St. Sele Measure	38		_					$\pm$		$\pm$
7 23 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Total of the state				4.			$\vdash$	+	•		-	$\vdash$	+
3485455	Mattatage to the continue with the	F 1 2		MES Income pell leads per league		EMIF .,,t .=t .=t t,===1		$\vdash$	+				$\vdash$	+
24834-8 ME3	Fernanda I I I I I I I I I I I I I I I I I I I	F 1 2		To be could be shall colored the sould be could be copped to see a substantial beautiful to the second section of the section o		BMIF = 1						,		
7 2318 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		FB 34834-1 mode digital to/FE31 [8378]	·····	34834-1 in the control of the contro		T# (-1-1-1								
27 310 1002112 BE MES Silved	**************************************					Filler Beer West [resulter, Bester].			-			•		$\pm$
1 ME4	Edito lalipant - Broom of Block cal fraction for the first agency process Editor cal opposite for access the first			Common a MC4 M In constable HeTerological control of the Special or copyright of SCWSC and decrease a MC4 Single print and opening \$8.312 to be interested in a control of the Scwsc and the control of the Scwsc and the control of the Scwsca and th		top top s/MCS							$\vdash$	+
TE 4212		Education 1: 4313			,.	Politica proposa		$\Box$	-F				H	=
27 5210 per see se me 4 7 11111	Enter the selection of	1.2	*****	T84313, I.e., e e	3.	#11-1- = 11		$\vdash$	•					+
1t 7 32 10 11 MC3 E1111				81 3834-84-13 81 3834-84-13				$\Box$	-	+			$\Box$	=
778318 15 15 TE MES 1110		F 1, 188	*****	8  878   I  28.24-8  1887 86.776   786 43 -8.110   1817 80-7   10. jun  2824-8  10. 2824-84-11					•				Ш	
27 310 110 00 ME3 0	ed operate location and a second		atatic,						•			, ,	$\Box$	$\perp$
7 22 18 18 18 18 18 18 18 18 18 18 18 18 18			P.1.1.1			Print = 2822		ш	•	+	$\vdash$	+	ш	-
100/100 as Man 1100	- Pool de Bele peels process leannand	Eligina of BORS pool	·····		-:::	Politica: Politica: 2824 Politica: 2824 Politica: 2824 Politica: 2824			•					
,	College of Colored and								•	$\perp$		$\perp$	Ш	$\perp$
	Entre Consession and profession Et a 11 a Enception trained tr	Mattat2  ataptas	*****	BE43 tologopold proclemperal toland a/TE31	40	43886 -1 818 -1-1	-	Н	•	+	$\vdash$	+	Н	_
100 100 100 100 100 100 100 100 100 100		#11/10 11 34114-115		Boot object to become a MES.	,	24114-11 to loss of Block selection to the selection of t		$\vdash$	$\top$				$\vdash$	
Accept. France passes as Man									_					
/Table lasting Mes Testing	Edwards de control de			PMI to Containing to 27848, deploy over equality	30.6	F1 .11 = 8637 ME4. M.= F.1.   M11, 86		$\vdash$	+	+		+		
	State an example for preferring condition for a first bandware condition for the following property of the following property or agent as property or agent	to and in Fig. 1 but of the study for published ranging of had in Fig. 2 quantity for convolutionalists are	in the second	Stronger of the control of the CEPS.  But printed a part of Colorada, SC 37 ea/FC 13.  For printed a part of Colorada, SC 37 ea/FC 13.										
27 8318 88 MCS [8-11]	Edito leigeno - Enference En apolo les								$\pm$					$\pm$
	Eneloselo commente contre la lla luctera contre la elloca El-apola menollar (cl. 1ce cloca)			Is to be considered MCS and MCS, much to be questioned as a second secon		18488, 37886/37887/37888								
Hrandrand the amprof suppo	ling the clandardination reque	-1  11,												
77.0310 present to ME4 Press	#I=I-=I-I =-I;=;		######################################	MET AND		Proceedings of the opposite to 77 C21								
77 8218 CTR TE ME4 81111	Introduction Techniques - Bellin Integrand - Econo		atatra,	Bearing and a special to be plot up to taken Economics Black a BE43.				$\square$					$\sqcup$	
778318 (158875) WES 71811	le lie en		*****					$\vdash$	$\perp$			$\perp$	$\vdash$	$\perp$
27 8218   128 888	E-sp-1-s E-p			Boley on Boott Toolers Buyort ont 3834-18-34				$\vdash$	+				$\vdash$	+
77 8218   DESERTE TO MEN PARTIES	E-1		F						-			+		
79 100 100 100 100 100 100 100 100 100 10		Higher of 24822	P.1.1.1					$\vdash$	+			+	$\vdash$	+
TRAIL SATE TO MEN ENTE	legal Barrion legal Barrion et al la control d'Indianala publication de la control d			PMI a juguro. Condung t.j. submit is 42881 onl										
TR WEST PORTOR	T								-			-	$\Box$	$\pm$
27 8318 ME3 \$1			F	C									$\Box$	=
** MC3	E-11			Interest.				$\perp$						

## On ISO/IEC 42001: Management System Standard for Al

- 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 Al 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, enforcable requirements



#### **Approach in JTC21:**

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

				l				<u> </u>	L
	JT021011	prEN ISO/IEC		WG2	Marta	Information technology - Artificial intelligence - Management	Adoption of 42001	Preliminary	١
	11021011	42001		WGZ	Janczarski	system	Adoption of 42001	Premimary	it
					Adam Leon		Complements, and builds	Under	
	JT021039	prEN XXX	EN	WG2	Smith	AI - quality management system for regulatory purposes	on, several ISO/IEC	Drafting	
					Jillul		standards, including 42001	Draiting	L
v v I								4	



## **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

<u>Theory</u>: Consensus of "all relevant stakeholders"

including companies of all sizes, academia, civil society,

broad spectrum of countries, whole AI lifecycle, ...

<u>Practice</u>: 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 Al

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

- 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)
- => Al 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  • All types of AI  • Late stage of value chain	Requirements on General Purpose Models – Articles 53, 55  Generative AI only Early stage of value chain
Development context and process	<ul> <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> <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