

December 5th, 2024

Welcome to the webinar:
**Decoding the AI Act: European
Standards & the Future of AI regulation**

Agenda

- **13.00:** Welcome and introductions
- **13.10: Overview of the AI Act: Status, Timeline, and Challenges**
Dr. Tatjana Evas, Legal and Policy Officer at the European Commission
- **13.25: AI Act and the surrounding Legal Landscape**
By Jesper Løffler Nielsen, Associate Partner, Lawyer (L), Ph.D. FOCUS ADVOKATER
- **13.45: Navigating the Evolving Landscape of AI Standards**
By Ana Paula Gonzalez Torres, Ph.D. researcher at Aalto University and member of the Finnish Standardisation Association
- **14.00: AI Act from a SME Perspective**
By Anders Kofod-Petersen, founder and CEO of OptikosPrime, Ph.D. and professor in applied Artificial Intelligence at the Norwegian University of Science and Technology
- **14.20: AI Act Compliance from a Product Perspective**
By Luis Martinez, Ph.D. – Global AI Product Compliance Expert - ASSA ABLOY
- **14.40: Panel Discussion**

Moderator: Kim Skov Hilding, Head of the Danish Standardisation Committee on AI and secretary for CEN/CENELEC/JTC 21 Artificial Intelligence

Welcome from the organisers: the Nordic National Standardisation Bodies



EUROPEAN ARTIFICIAL
INTELLIGENCE OFFICE

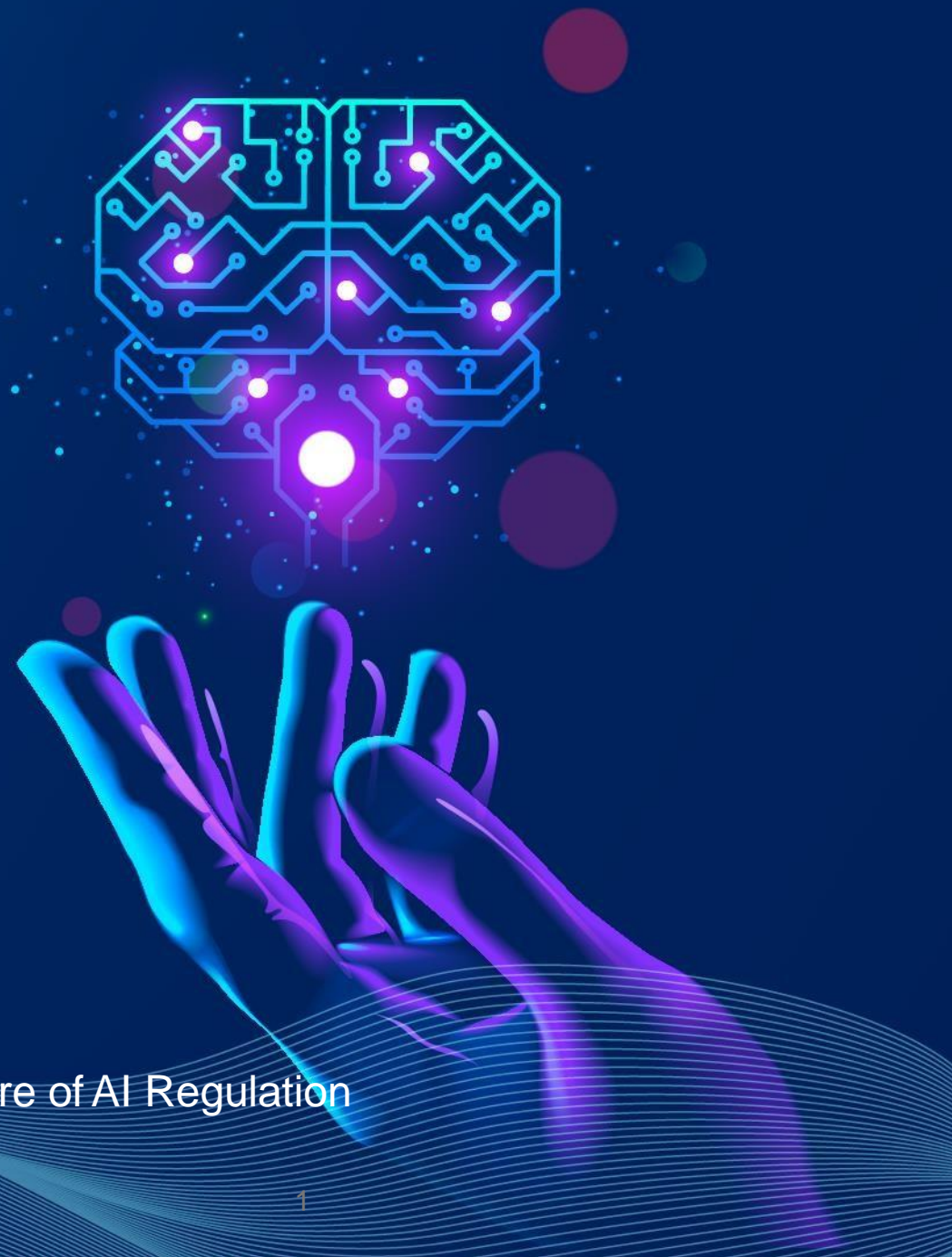


EXCELLENCE
& TRUST

Overview of the AI Act: Status, Timeline, and Challenges

Dr. Tatjana Evas,
DG CNECT, European Commission

Decoding the AI Act: European Standards and the future of AI Regulation
05/12/2024





1. The EU Artificial Intelligence Act

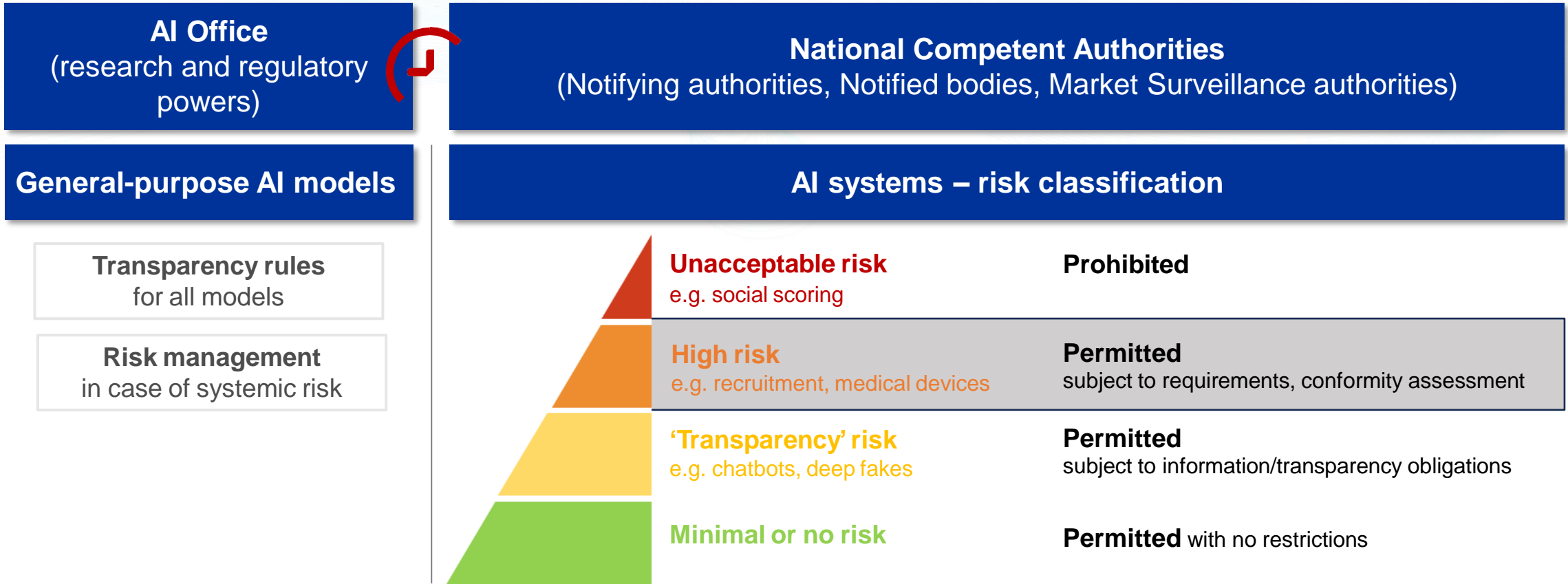


- **First comprehensive regulatory safety framework on AI globally**
- **Entered into force in August 2025; rules apply gradually as from February 2025**
- **Safety legislation** – to specifically address risks to health, safety and fundamental rights from certain uses of AI systems.
- **Horizontal regulation** – applies across the sectors and uniformly in 27 EU MSs.
- Founded on the **Risk-based approach** : sets the rules under which AI systems can be used (**4 categories of risk**)
- For high-risk AI systems, sets mandatory requirements (**pre and post market**) to be operationalized through **harmonized European standards**.
- Sets governance, enforcement and supervision systems and builds as much as possible on existing structures (e.g. conformity assessment procedure + market surveillance/enforcement)
- Establishes obligations for **General Purpose AI models** (two layers)





2. Risk-Based Approach



3 **Mandatory Requirements for all high-risk AI system before they can be used and strong system of enforcement and post-market monitoring**



3. Requirements

Mandatory Requirements for high-risk AI system before they can be used on the EU market

Provider is responsible for EU declaration of conformity + CE marking



(Harmonized) Standards:



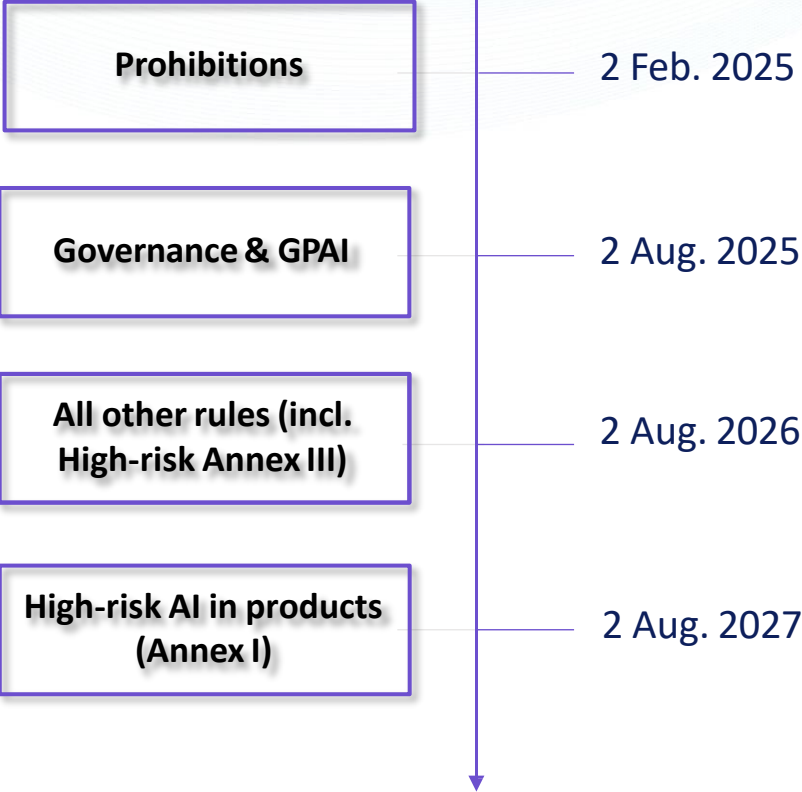
- Operational tools to support regulatory compliance with requirements
- Ongoing work in ISO/IEC SC-42 and CEN/CENELC JTC-21. The main principle ‘international first’ i.e. build on IEC/ISO work as much as possible, however, as long as the international standards are aligned with the AIA Objectives and approach and cover same type of risks



4. The ongoing work and priorities

Entry into
force:
1 Aug.
2024

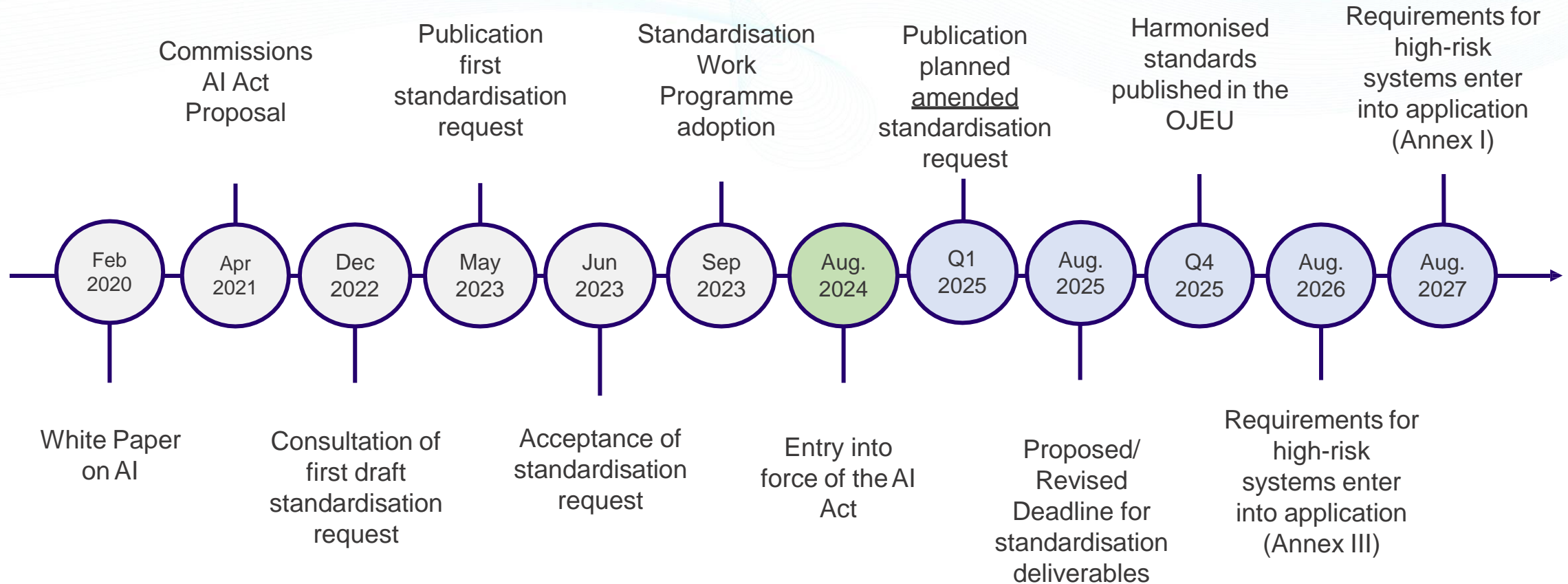
- ▶ **Setting up the governance structure**
(AI Office, AI Board, Scientific Panel and Advisory forum)
- ▶ **Coordinating drawing up of Code of practice on General-Purpose AI**
- ▶ **Preparation of standards for high-risk requirements (CEN/CENELEC)**
- ▶ **Preparing guidelines, implementing and delegated acts**
(e.g. on definition of AI system, prohibitions, high-risk use cases, transparency)
- ▶ **Support for the establishment of AI regulatory sandboxes**
to promote innovation and regulatory learning



The AI office launched **AI Pact** to support companies and other organisations in the implementation and foster anticipated application of the AI Act



5. Timeline for adoption of standards



Additional standardisation requests may be issued in the future



6. Challenges and Opportunities

Tailored to Objectives of the AI Act

Prioritise risks to health, safety and **fundamental rights** over broader organisational risks.

Oriented to Product Safety

Prioritise **technical requirements** that apply to AI systems, covering their entire lifecycle and ensure **quality**

Sufficiently prescriptive and clear

Include prescriptive requirements that are clear, precise, actionable, **measurable and verifiable**

Applicable across sectors and systems

Horizontal requirements that apply to a large number of AI systems and sectors.

Aligned with the state of the art

Consider the architecture, components and risks of modern AI systems

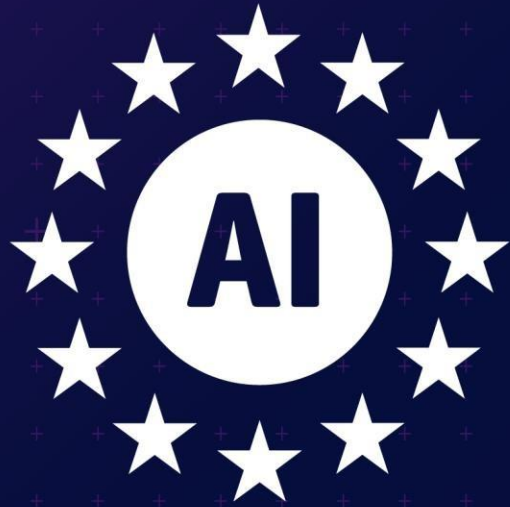
Cohesive and complementary

Consider the interplay between requirements, facilitate joint application of resulting standards

New Challenge +
emerging state of the art

Inclusiveness

Time



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Thank you!

Tatjana.evas@ec.europa.eu



5. Governance



Rules for AI systems



National level:
EU Member States to designate national supervisors

EU level:
The European Data Protection Supervisor oversees systems used by EU institutions, bodies and agencies



AI Board

with EU Member States to coordinate at EU level



Scientific Panel

supports with independent technical advice



Advisory Forum

supports with stakeholder input

Rules for general-purpose AI models



EU level:
AI Office within Commission

Overview of the AI Act: Status, Timeline, and Challenges

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AI Act and the surrounding Legal Landscape

By Jesper Løffler Nielsen, Associate Partner, Lawyer (L), Ph.D. FOCUS

ADVOKATER

Starting point...



...but certain aspects of AI necessitates new regulations

EU Commission “*Whitepaper on AI*” (2020)

“5. AN ECOSYSTEM OF TRUST: REGULATORY FRAMEWORK FOR AI

“As with any new technology, the use of AI brings both opportunities and risks...”

“When designing the future regulatory framework for AI, it will be necessary to decide on the types of mandatory legal requirements to be imposed on the relevant actors...”

“While the EU legislation remains in principle fully applicable irrespective of the involvement of AI, it is important to assess whether it can be enforced adequately to address the risks that AI systems create, or whether adjustments are needed to specific legal instruments.”

“Improving access to and the management of data is fundamental. Without data, the development of AI and other digital applications is not possible.”

- A number of new legal acts and revised rules focusing on AI and data, e.g. **AI Act, AI Liability Act, Data Governance Act, Data Act etc.**
- + Specific rules on AI/algorithms in e.g. **Digital Services Act, Machinery Regulation, General Product Safety Regulation etc.**

AI Act – From a lawyer’s perspective

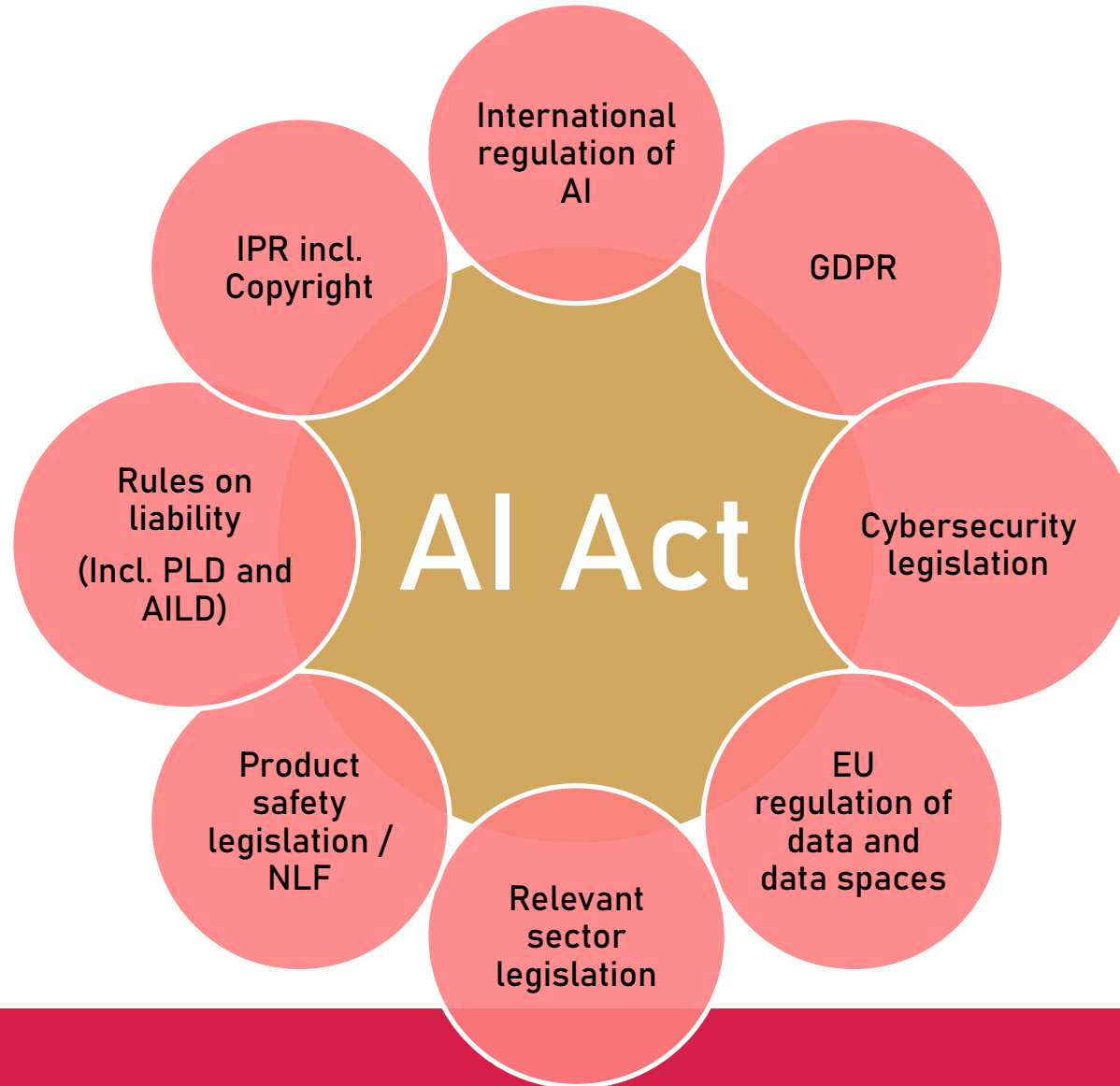
Purpose – art. 1(1)

*“to improve the functioning of the internal market and promote the uptake of **human-centric and trustworthy artificial intelligence** (AI), while ensuring a high level of protection of **health, safety, fundamental rights** enshrined in the Charter, including democracy, the **rule of law** and **environmental protection**, against the harmful effects of AI systems in the Union and **supporting innovation**.”*

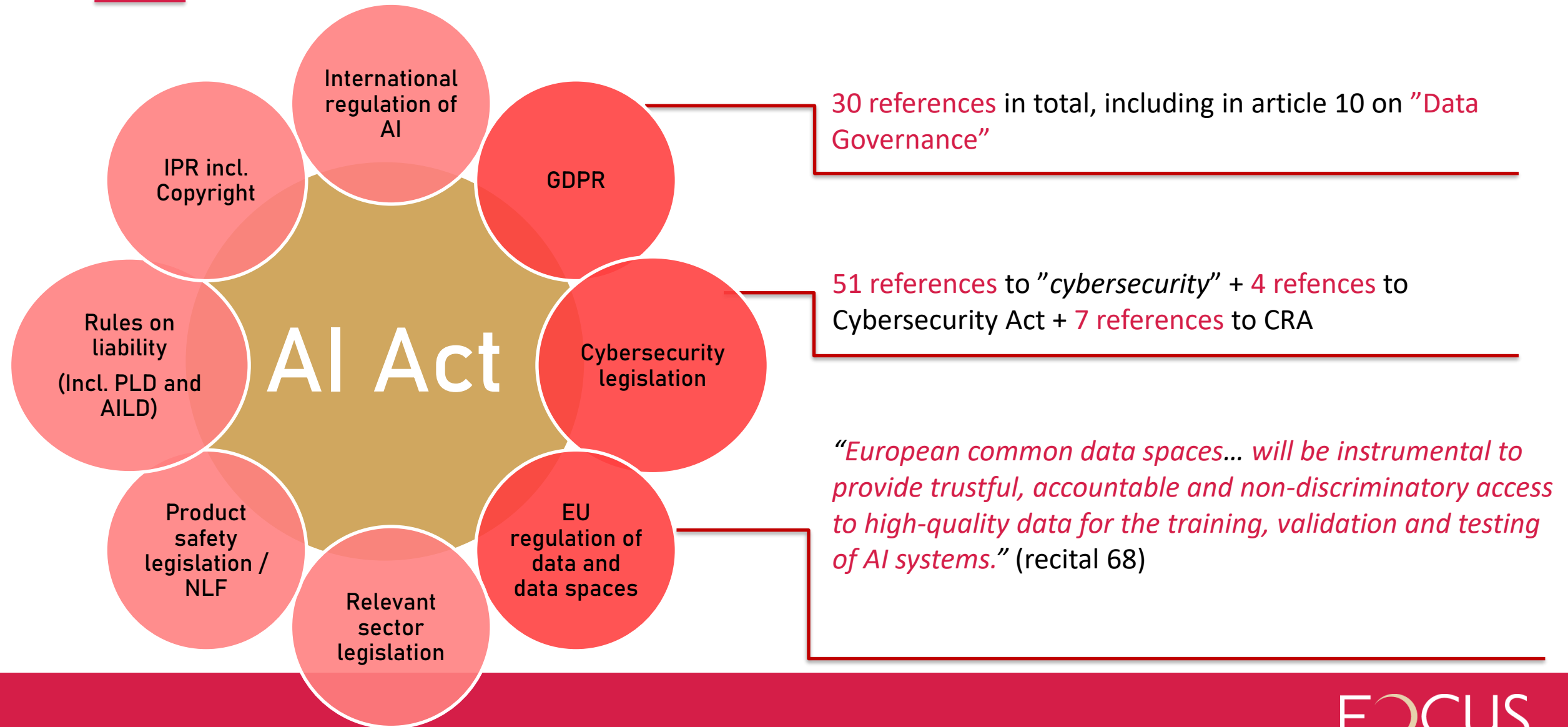
Key facts

- Type of regulation: A never before seen combination of **product safety legislation** (NLF) og **protection of fundamental rights**.
- Risk based: Requirements depend on **overall risk**
- Obligations for: **“Providers”, “Deployers”, “Importers”, “Distributors”** etc.
- Enforcement: Both at EU level (**“European AI Board”** and **“AI Office”**) and national level (e.g. for DK: **Digital Government Agency + Data Protection Agency**)
- Timeline: Adopted summer 2024. Comes into force gradually from February 2025 and onwards.

AI Act and the surrounding legal landscape



AI Act and the surrounding legal landscape

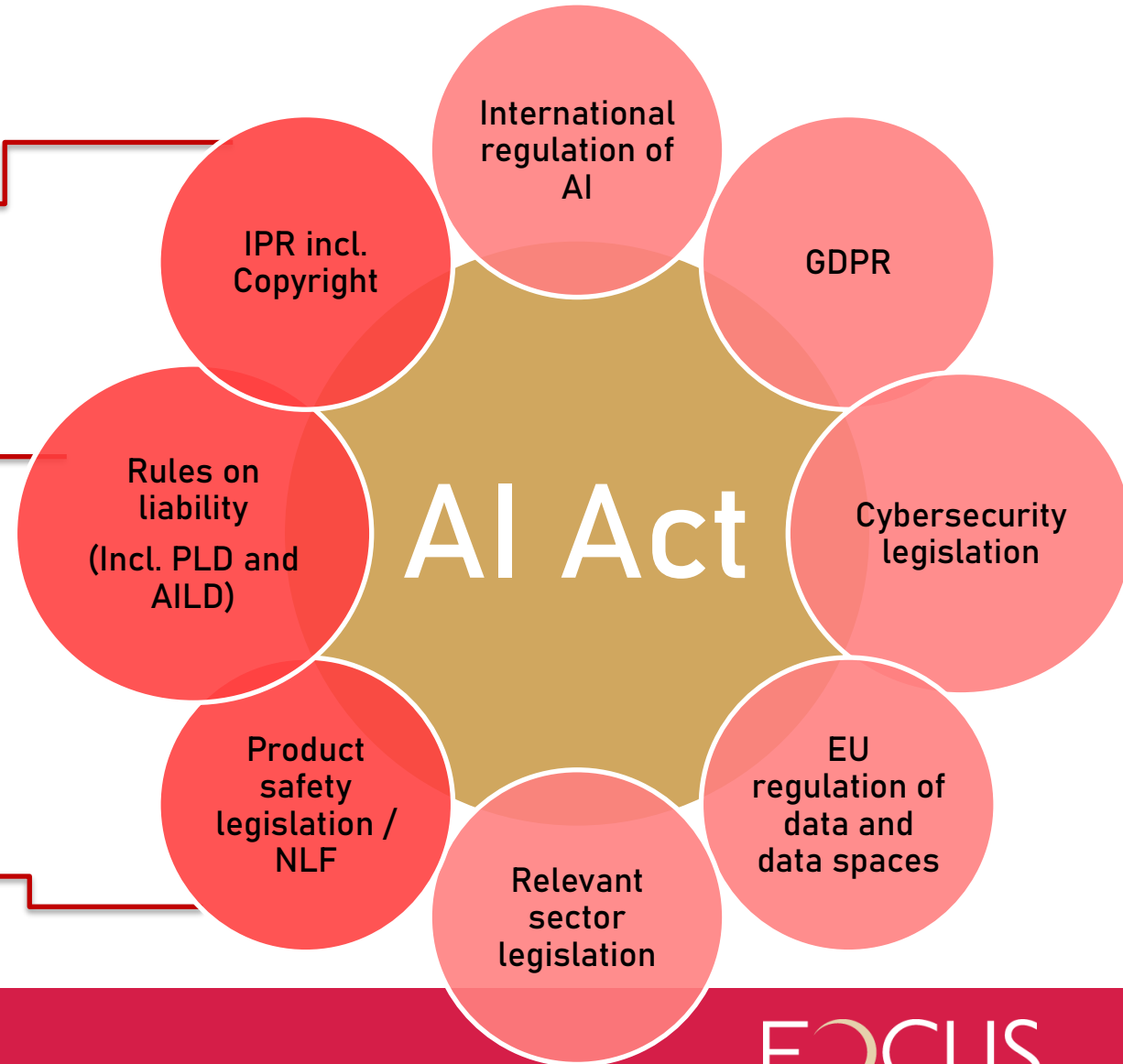


AI Act and the surrounding legal landscape

16 references to "copyright", including express obligations for GPAI-model providers in article 53

Express reference to rules on liability including the revised Product Liability Directive (PLD) in recital 9

...New Legislative Framework... to which this Regulation is complementary." (recital 9)



Overlap between GDPR and AI Act

GDPR principle* / requirement	AI Act principle** / requirement
Lawfulness	Express reference to the need for a valid legal basis for training data, e.g. article 10(5)
Fairness	E.g. Fundamental Rights Impact Assessment
Transparency	E.g. art. 13 (towards deployers) and 50 (towards end-users)
Purpose limitation	E.g. art. 10(2) and recital 69
Accuracy	E.g. art. 10(3) and 15
Security (integrity and confidentiality)	E.g. art. 9 (risk management) and 15 (robustness and cybersecurity)
Accountability and ROPA's	E.g. art. 4 (AI literacy) and art. 10 (Data Governance)
Limitations of Automated Decision making	E.g. art. 14 (Human Oversight)
Risk assessments / DPIA	E.g. art. 43 (Conformity assessments) and art. 27 (Fundamental Rights Impact Assessment)

* GDPR art. 5 - ** AI Act recital 27

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* GDPR art. 5 - ** AI Act recital 27

... but also substantial differences

GDPR	AI Act
Technology neutral	Technology specific
Primarily focused on Fundamental Rights	Primarily focused on product safety (supplemented with Fundamental Rights)
Most requirements are broad and open-ended	Some requirements are open-ended, but most are specific
0 annexes with details	13 annexes
0 harmonized standards	10 (?) upcoming harmonized standards

QUESTIONS?



International regulation of AI

- **OECD:**
 - [AI Principles](#) (2019)
 - [Definition of AI](#) (November 2023 update)
- **Council of Europe:**
 - [Recommendation of the Committee of Ministers to member States on the human rights impacts of algorithmic systems](#) (2020)
- **Trade and Technology Council (TTC) (EU/US)**
 - [Roadmap](#) (2022) + [AI taxonomy](#) (2023)
- **G7:**
 - ["International Draft Guiding Principles for Organisations Developing Advanced AI systems"](#) (October 2023)
 - [Statement on the Hiroshima Process](#) (October 2023)
- **Countries attending the AI Safety Summit:**
 - [The Bletchley Declaration](#) (November 2023)
- **UK:**
 - [A pro-innovation approach to AI regulation - GOV.UK \(www.gov.uk\)](#) (March 2023)
 - [Artificial Intelligence \(Regulation\) Bill \[HL\] - Parliamentary Bills - UK Parliament](#) (November 2023)
- **US:**
 - [Blueprint for an AI Bill of Rights](#) (October 2022)
 - [Executive Order to Strengthen Racial Equity and Support for Underserved Communities Across the Federal Government](#) (February 2023)
 - [White House "Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence"](#) (October 2023)

→ Approaching consensus on: 1) **AI risks**, 2) **(softlaw) principles** og 3) **Termonology**

Jesper Løffler Nielsen



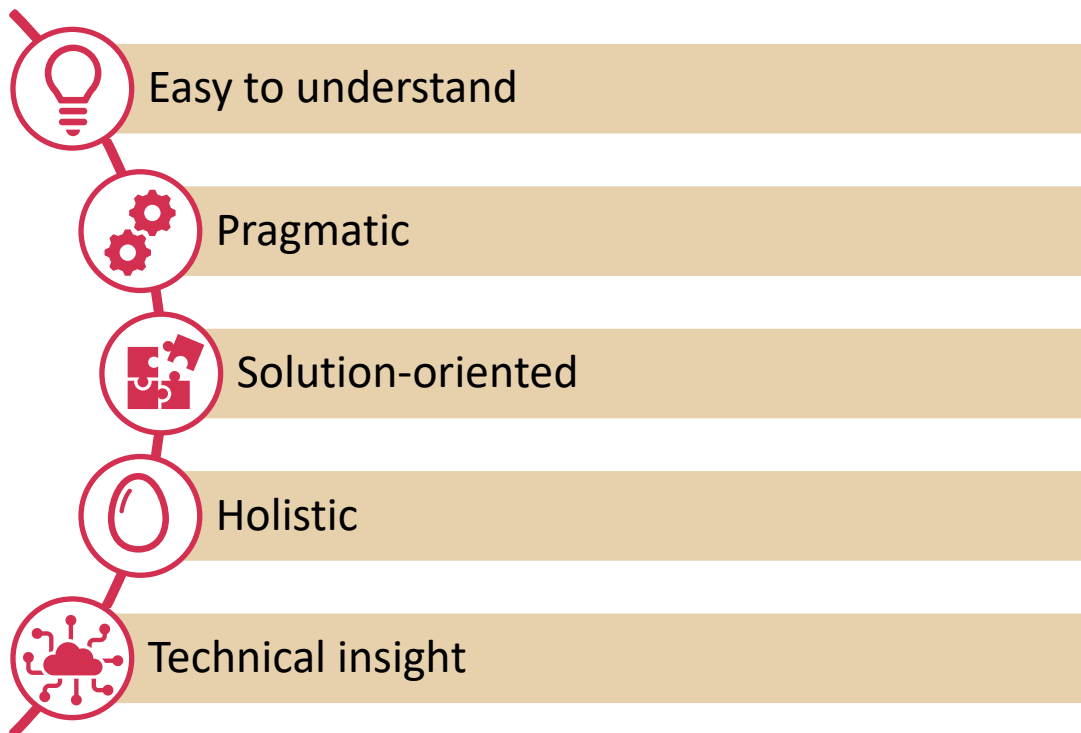
Profile

- Certified IT-attorney and PhD in IT Law
- Team lead of "Tech Team" at Focus Advokater P/S

Relevant experience

- Board member of Danish IT-Attorneys
- "*Innovation & Compliance*" – Network and conference on digital compliance
- EDPB "*Pool of Experts*" on digital technologies
- Member of Danish Standards' "*AI committee*" (S-855)
- A number of publications within IT Law, including regulation of data and AI

Our advice



Our areas of expertise:

- **Data protection law**
 - GDPR
 - Practical compliance
- **Cybersecurity law**
 - NIS2, CER, DORA, CRA, etc.
 - Practical compliance
- **IT-contract law**
 - IT contracts, including development, service, reseller and cloud contracts
 - Agreements related to data, AI, robots, drones, IoT, etc.
- **Digital regulation**
 - Data Governance Act, Data Act, AI Act, Digital Services Act etc.
- **Online marketing**
 - The complex interplay between GDPR, marketing law, cookie rules and sector regulation

Navigating the Evolving Landscape of AI Standards

By Ana Paula Gonzalez Torres, Ph.D. researcher at Aalto University and member of the Finnish Standardisation Association



NAVIGATING THE EVOLVING LANDSCAPE OF AI STANDARDS

AI ACT WEBINAR

ANA PAULA GONZALEZ TORRES

DOCTORAL RESEARCHER AT AALTO UNIVERSITY

MEMBER OF THE FINNISH STANDARDISATION ASSOCIATION

OVERVIEW

- Technical standards define concrete approaches that can be adopted to meet regulatory requirements in practice.
- European harmonised standards for the AI Act:
 - Standardisation request
 - Published in the Official Journal of the EU = Presumption of conformity
- European standardisation organisations:
 - CEN
 - CENELEC
 - ETSI
- International standardisation activities from ISO and IEC can be adopted or adapted in the European context based on international agreements (Frankfurt, Vienna).

STANDARDISATION REQUEST

- Standards must address and prioritise the **risks** that AI could pose to the health, safety, and fundamental rights of individuals.
- System and product-centric view.
- All phases of the product lifecycle
- Standards should capture in precise terms the processes, techniques and methods needed to make AI systems trustworthy in a verifiable manner
 - Ensuring to address all identified risks in line with regulation
 - Mindful of the implementation burden
- Horizontal requirements
 - + Specific sectors
 - + Specific types of systems
- High-risk AI systems (incl. GPAI systems)

STANDARDISATION DELIVERABLES

- Expected by 2025/2026
- Request by the European Commission cover 10 concrete aspects of AI:
 - 1) Risk Management
 - 2) Data Governance and Quality
 - 3) Record Keeping
 - 4) Transparency
 - 5) Human Oversight
 - 6) Accuracy
 - 7) Robustness
 - 8) Cybersecurity
 - 9) Quality Management
 - 10) Conformity Assessment



AVAILABLE STANDARDS

- Homegrown European standard
 - CEN/CLC/TR 18115:2024 - Data governance and quality for AI within the European context
- Standards adopted from the global ISO/IEC standardisation committee SC 42
 - ISO/IEC 25059:2024 – SQuaRE – Quality model for AI systems
 - ISO/IEC 23894:2024 – Guidance on risk management
 - ISO/IEC 8183:2024 – Data life cycle framework
 - ISO/IEC 22989:2023 – Artificial intelligence concepts and terminology
 - ISO/IEC 23053:2023 – Framework for AI Systems using ML
 - ISO/IEC/TR 24027:2023 – Bias in AI systems and AI aided decision making
 - ISO/IEC/TR 24029-1:2023 – Assessment of the robustness of NNs – Part 1: Overview
 - ISO/IEC/TS 12791:2024 – Treatment of unwanted bias in classification and regression ML tasks

STANDARDS IN DEVELOPMENT

- Key standards:
 - 1) AI trustworthiness framework
 - 2) AI risk management
 - 3) Quality management for EU AI regulatory purposes
 - 4) Conformity assessment

- Informative Annexes ZA, ZB or ZZ

Establish the relation between the standards and the essential requirements of the AI Act.

Under Approval	Under Drafting
AI Conformity Assessment	AI concepts and terminology
Environmental sustainable AI	Framework for AI using ML
Transparency taxonomy of AI systems	Overview of AI tasks and functionalities related to NLP
Data quality for analytics and ML –	Evaluation methods for accurate NLP systems
Part 1: Overview, terminology, and examples;	AI system logging
Part 2: Data quality measure;	SQuaRE – Quality model for AI systems
Part 3: Data quality management requirements and guidelines;	Taxonomy of AI system methods and capabilities
Part 4: Data quality process framework	Concepts, measures and requirements for managing bias in AI systems
	Quality and governance of datasets in AI
	AI Conformity assessment framework
	Competence requirements for AI ethics professionals
	Quality management system for EU AI Act regulatory purposes
	AI trustworthiness framework
	AI Risk Management
	AI-enhanced nudging
	Cybersecurity specifications for AI systems

WHO CREATES STANDARDS?

Subject to continuous evaluation by the European Commission:



Standards build on the consensus of a substantial number of stakeholders

Standardisation request explicitly demands measures to facilitate participation from all sectors and types of organisations

- Large industry players
- SMEs
- Societal stakeholders
- Representative of authorities
- Universities and research institutes



CEN/CLC/JTC 21 Working groups (WG)

WG1: Strategic Advisory Group

WG2: Operational aspects

WG3: Engineering aspects

WG4: Foundational and societal aspects

WG5: Joint standardisation on Cybersecurity for AI systems

HOW TO PARTICIPATE?



- Standardisation groups monitor and participate in the global (ISO) or European (CEN) standardisation of their field and influence it according to the needs of stakeholders.
- How can individuals and organisations contribute to the creation and refinement of standards?
 - National expert group for standardisation
 - 1) Join the AI standardisation working group
 - 2) Follow the progress of standardisation
 - 3) Comment on standard proposals

RESOURCES

- [CEN/CLC on Artificial Intelligence](#)
- [CEN/CLC/JTC 21 Published Standards](#)
- [CEN/CLC/JTC 21 Work programme](#)
- [AI Standardisation Inclusiveness JTC 21 Newsletter](#)
- European Commission. Commission Implementing Decision of 22.5.2024 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence. C(2023) 3215 final.
- Gonzalez Torres, A. P., & Ali-Vehmas, T. (2024). [Governing through Standards: Artificial Intelligence and Values](#). 28th EURAS Annual Standardisation Conference, Delft University of Technology, Delft, The Netherlands.
- Soler Garrido, J., De Nigris, S., Bassani, E., Sanchez, I., Evas, T., André, A., & Boulangé, T. (2024). Harmonised Standards for the European AI Act. European Commission, Seville, JRC I 39430.

AI Act from a SME Perspective

By Anders Kofod-Petersen, founder and CEO of OptikosPrime, Ph.D. and professor in applied Artificial Intelligence at the Norwegian University of Science and Technology

AI Act from a Product Compliance Perspective

By Luis Martinez, Ph.D. – Global AI Product Compliance Expert – ASSA ABLOY

The ASSA ABLOY Group is the global leader in access solutions. Every day we help people feel safe, secure and experience a more open world.

Navigating the AI Act Compliance from a Product Perspective

Luis Martinez, Ph.D. (luis.martinez3@assaabloy.com)
Global AI Product Compliance Manager

Experience a safer and more open world



Safety first



Alarm



Assembly point



Emergency exit



Emergency number



First aid kit



Protective equipment

Agenda

Global regulatory context

Key Provisions and Objectives of the EU AI Act

Challenges in AI regulation and compliance area

Strategies for Navigating Regulatory Complexities

Brussels Effect

Conclusions



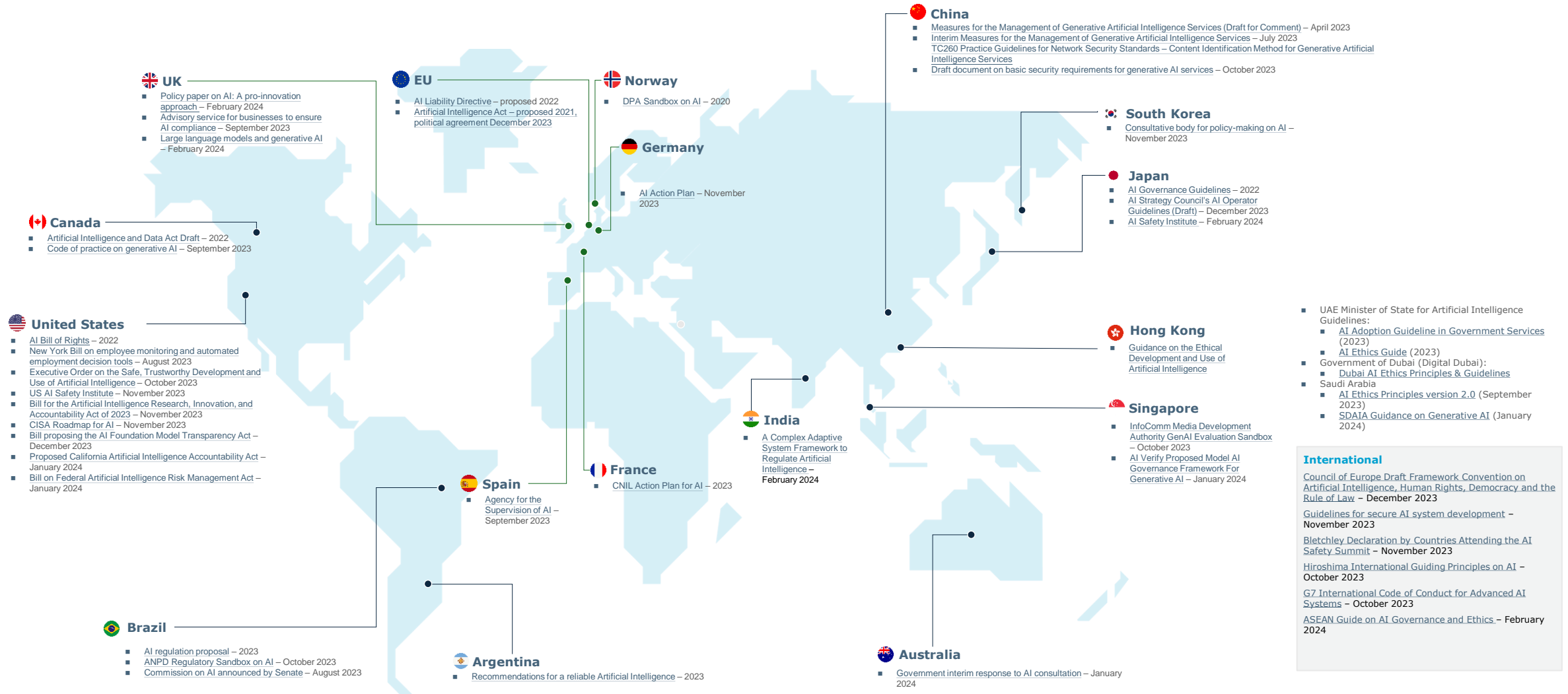
Global AI Regulations Policy

An overview by country

Sources:

- Baker & McKenzie. (Apr 2024). *AI Governance and the AI Act*
- OECD AI Policy Observatory. (Apr 2024). *Global: OECD AI Policy Observatory*

This map shows only some of the specific AI regulation that is emerging around the globe. Other existing regulation (adjacent legislation), such as discrimination legislation and data privacy, also applies to AI.



AI Policy & Legislation Commonalities

Risk based approach and Impact Assessment. (AI Governance Foundation)

- Risks should be managed during the AI System Lifecycle
- High-Level Impact Assessment to triage

Transparency in the AI-human interaction

- Use of AI should be communicated/clearly visible

Security

- Wider concept to ensure both resilience and availability
- Ensure protection of data and consider specific security risks

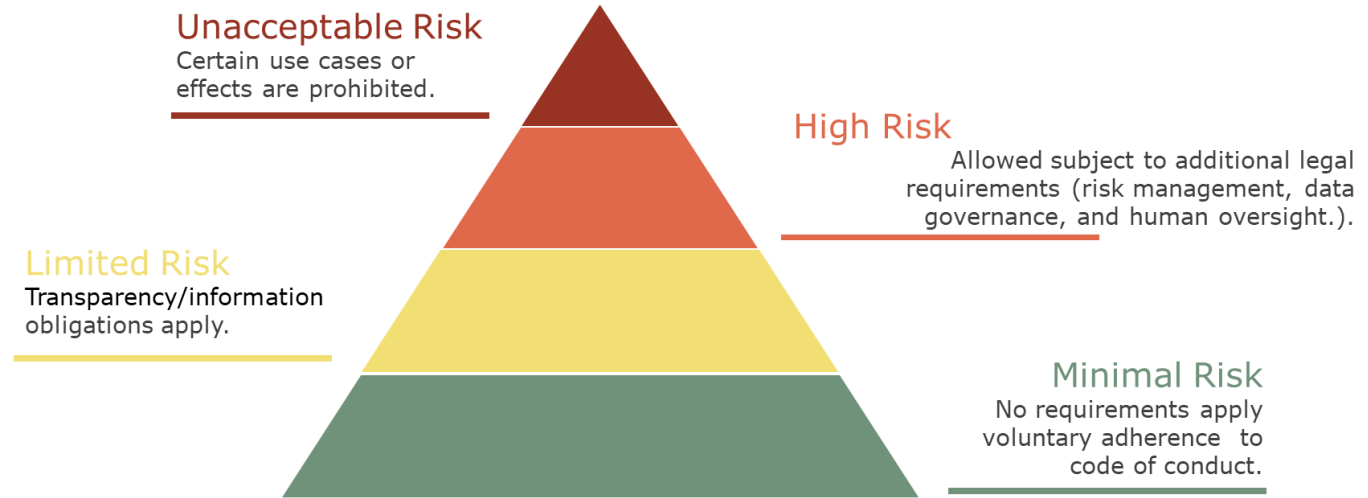
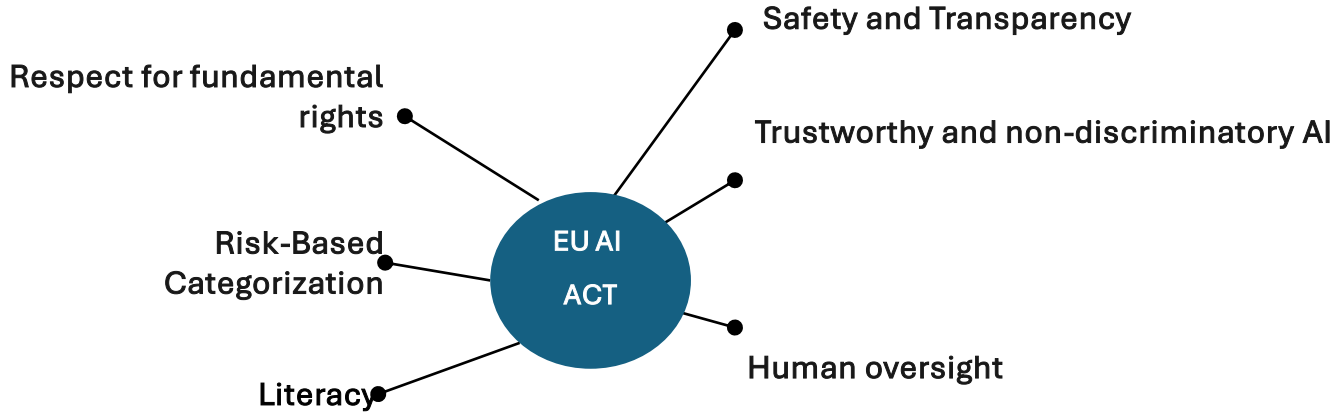
Traceability in relation to data sources

- Ensure rights to data use
- Ensure operations on data are leading to validity and quality of outputs

Human Rights Protections

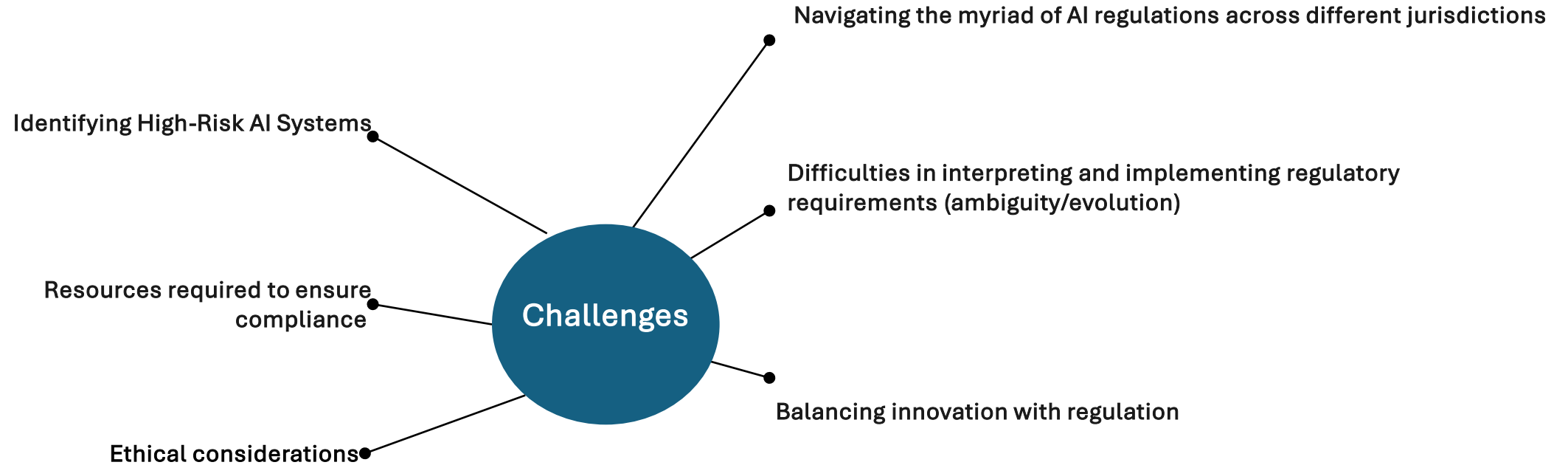
- Human autonomy and integrity
- Prevention of algorithmic bias
- Privacy, protection of sensitive attributes
- Sustainability

Key Provisions and Objectives of the EU AI Act



Compliance Requirements → Conformity Assessment → Standards (Target High Risk but important to be consider with Limited/Minimal Risk)

Challenges in AI regulation and compliance area



Strategies for Navigating Regulatory Complexities

1 Best Practices for Implementing AI Governance.

2 **Adapting to Different Organizational Contexts**

3 Continuous Improvement and Learning

4 Tools and Frameworks for Risk Assessment (standards)

Best Practices for Implementing AI Governance



Providing training and resources to employees on responsible AI practices.

Implement robust processes for monitoring and auditing AI systems to ensure compliance with regulations and standards.

Engage with stakeholders, including regulators, customers, and industry peers, to stay informed about regulatory changes and best practices

Establish clear AI governance policies + AI-specific risk assessment tools and frameworks to identify, evaluate, and mitigate potential risks associated with AI systems.

Adapting to Different Organizational Contexts



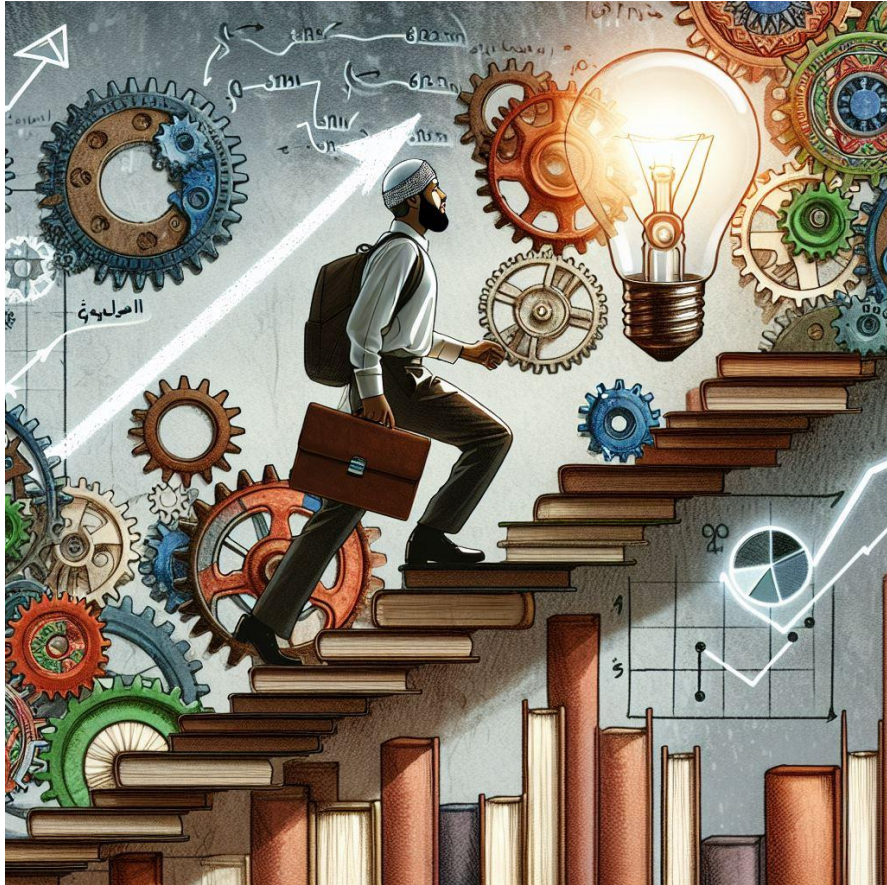
Tailor AI governance strategies to fit the unique needs and contexts of your organization.

Develop flexible and scalable governance frameworks.

Encourage cross-functional collaboration to ensure a holistic approach to AI governance

Continuously evaluate and refine AI governance practices to address new challenges and opportunities as they arise.

Continuous Improvement and Learning



Foster a culture of continuous improvement by regularly reviewing and updating AI governance policies and practices.

Encourage ongoing learning and development to stay informed about the latest regulatory developments and best practices in AI governance.

Implement feedback mechanisms to gather insights from stakeholders and use this information to enhance your AI governance efforts.

Stay engaged with industry forums, conferences, and working groups to share knowledge and learn from the experiences of others.

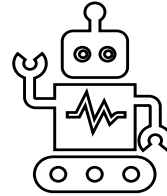
Relevant Standards Developed by ISO/IEC



ISO/IEC 22989

Artificial intelligence concepts and terminology

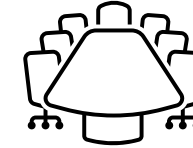
Establishes a comprehensive vocabulary for AI concepts and terminology



ISO/IEC 23053

Framework for AI Systems Using Machine Learning

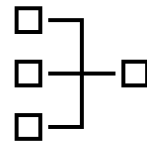
Provides a framework for describing AI systems using ML technology
Outlines system components and functions within the AI ecosystem



ISO/IEC 42001

AI Management Systems

Specifies requirements for an Artificial Intelligence Management System (AIMS)



ISO/IEC 27001

Information Security Management Systems

Defines requirements for information security management systems (ISMS)

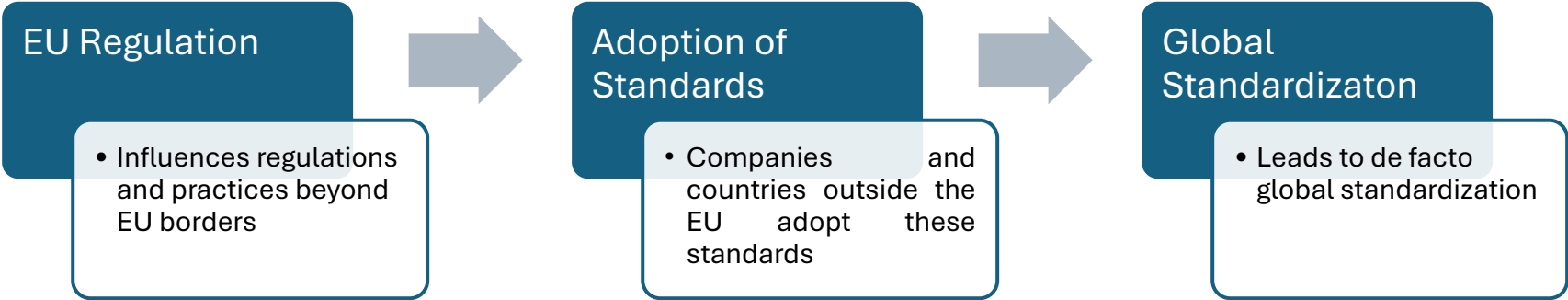


ISO/IEC 38505-1

Application of ISO/IEC 38500 to the governance of data

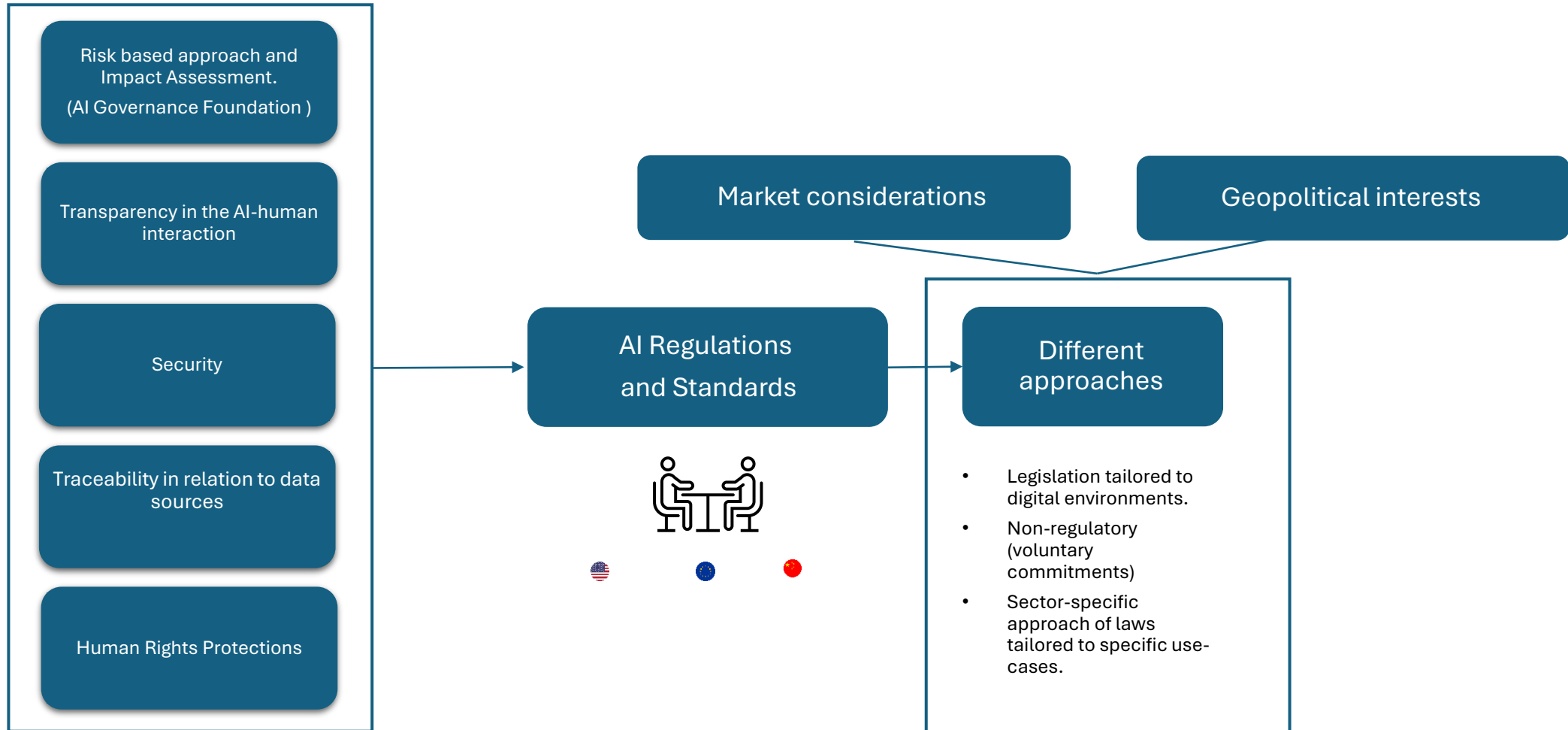
Provides guiding principles for the governance of data within organizations

Brussels Effect



- **GDPR**
- **High bar for data protection**
- **California Consumer Privacy Act (CCPA)**
- **Data protection laws in Asia, LATAM**

Regulatory discussion



Potential Benefits of the Global 'Brussels Effect'

1 Increased trust and market opportunities

Opening new market opportunities.

3 Promotion of Innovation

Driving innovation in developing safe, reliable, and ethical AI technology.

2 Harmonization of standards

Reducing complexity and cost of compliance.

4 Competitive advantage

Proactively alignment can attract customers and partners who value these principles.

What to Expect in the Compliance World



Increased regulatory scrutiny.

Adoption of standards globally.

Need to implement robust governance frameworks.

Continuous monitoring and adaptation.

Importance of Staying Informed and Compliant

1 Avoid legal and financial penalties

Keeping up with AI regulations prevents legal and financial risks.

3 Quick adaptation

Knowing about regulatory shifts helps businesses adapt and stay ahead.

2 Ensure responsible and ethical use of AI

Adhering to regulations guarantees responsible and ethical AI use.

4 Building trust

Adhering to regulations builds trust and strengthens the organization's reputation.



Thank you
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Experience a safer and more open world

Panel Discussion

With Louis Martinez, Kim Skov Hilding, and Lars Erik Jensen