UN WP.6 Bureau (and all subgroups) - Project Launch Meeting

Regulatory compliance of Products with embedded Artificial intelligence or other Digital technologies

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UNECE WP.6

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Introduction

Welcome & Thank you to all expert group members!

Please introduce yourself and state your

- **Name**
- **Organisation**
- **Sector**
- **Country**

Background

Nov 2020
Initial AI Discussion UNECE GRM

Jul 2021
Suggestion of a high-level UN Rec

Dec 2021
Mapping of International AI Regs

Apr 2022
Challenges & Responses Standards map

21 Apr 2023
Project Launch Session

Project timeline & evolution

AiNR-Tech market & Regulatory initiatives
May 2021

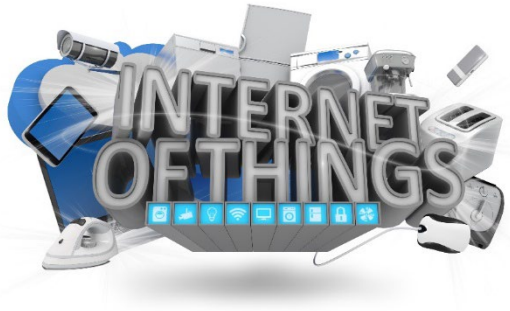
AI Risk, Incidents & Way forward
Sep 2021

Analysis of UN recs to date & Gap analysis
Feb 2022

UN AI Rec
Project Proposal
Jan 2023

WP.6

WP.6 - Horizontal AI Project Launch

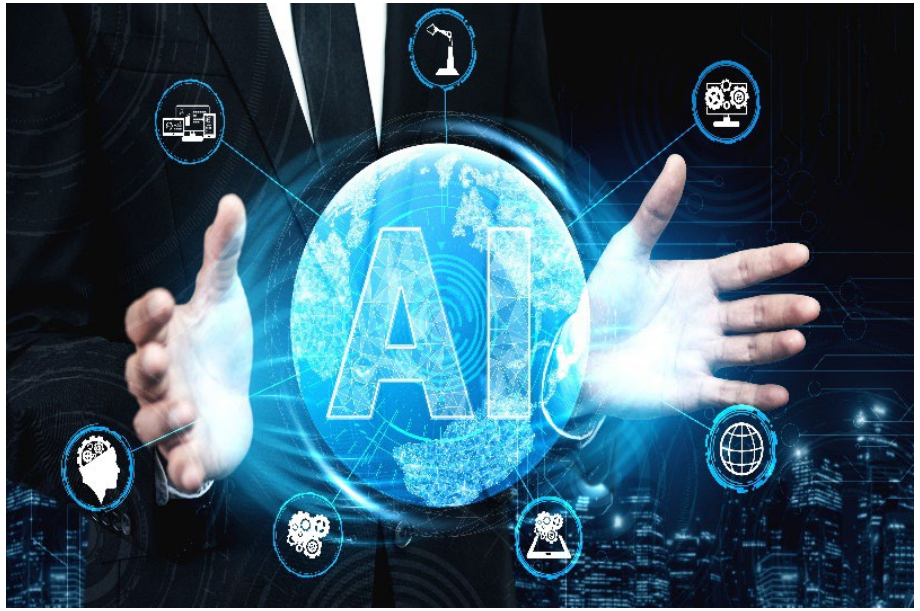


- **Title**: ***"Regulatory compliance of Products with embedded Artificial intelligence or other Digital technologies"***
- **Reach**: Horizontally, across all four subgroups (GRM, GRS, MARS & START)
- **Aims**:
  1) **UN Recommendation** (ca. 3-5 pages) on "**Product compliance with integrated AI and other digital technologies**"
  2) **UN Guidance document** (ca. 40 pages) for **effective technical regulation, regulatory impact assessment & regulatory cooperation**
- **Deliverables**:
  - Clear **definition of Artificial intelligence** within a product context
  - Clear **definition of Software embedded into products**
  - Whole **product lifecycle** consideration within digital regulation context incl. *Risk Management, Standards, Conformity assessment, Surveillance, Metrology*
  - Provide **guidance** how **to balance** the multitude of **various regulatory objectives**
  - Consider **cross-sectoral impact assessments** / **horizontal digital frameworks**
- **More information**: https://unece.org/trade/wp6/Projects#accordion_4

International project team

UNECE WP.6 Representation

- **International project working group**
- **From a large selection of different sectors**
- **With horizontal representation / reporting:**
  - GRM
  - GRS
  - MARS
  - START
- **Key areas of work:**



External experts

- Informal / non-committal conversations with **Prof. Stuart Russell OBE**, specifically wrt. **definitions** (https://cs.berkeley.edu/news/2021/06/stuart-russell-named-officer-most-excellent-order-british-empire)

We will be identifying & reaching out to further experts as and when needed.

Thematics

International Standards

Conformity assessments

Market surveillance

Definitions

Horizontal digital frameworks

Product compliance

Legal requirements

Sector-specific regulation

Human-centric technology

Traceability & Validation

Agile/ flexible regulation

Sustainable development goals

Safety & security risks

UN values & Fundamental rights

Metrology

Protection as fundamental right

Minimising digital divide

Reliable & accurate decisions

Children's rights

Gender-responsive

Complaints & Compensation

Border compliance

Customs & Trade disruption

Effective Risk management

Definitions

[DRAFT]

Technical regulation

“Regulation of products as defined by the WTO TBT Agreement(1), through technical regulations, standards and requirements on conformity assessment.”

Artificial intelligence

“A **product with an artificial intelligence system** (AI system) means a product with an embedded system, that operates with varying levels of autonomy and can make decisions influencing real or virtual environments, in a way that is generally intended to further human objectives.”

Software

“A **product with integrated software** means a product with an embedded system that controls the functioning of the product and directs its operation.”

Embedded digital technologies

“**Products with other embedded digital technologies** such as software and/or AI may also be connected to central or decentralised systems monitoring and/or controlling real or virtual environments that these products operate in.”

Risk

“A **product characteristic to be addressed by technical regulation** and that may concern product safety, cybersecurity, resilience, privacy, climate and sustainability (or a combination of these).”

(1) WTO Agreement on Technical Barriers to Trade

International Standards

[DRAFT]

Recognising that internationally agreed general terms and their definitions are indispensable for developing international regulatory cooperation in the field of AI

Taking into account the wide range of regulatory uncertainties present within AI Products.

Taking into account existing international standards relating to

- the management of risk , such as ISO 31000:2009 and ISO 31000:2018,
- artificial intelligence , such as ISO/IEC TR 24028:2020, ISO/IEC TR 24027:2021 and OECD's Principles on AI,
- conformity assessments, such as ISO/IEC 17000:2004,
- quality management systems, ISO 9001:2008,

and other standards, including product-specific standards, principles and recommendations.

Conformity assessments

[DRAFT]

Recognising that conformity assessment procedure results (e.g., calibration, testing, inspection, certification, and accreditation) for AI Products should be accepted by means of multilateral agreements, as described in **Recommendation G**.

Market surveillance

Recognising that good market surveillance policies and practices for AI Products placed on the market or imported meet legal requirements on safety, health, environment, fair competition between economic operators, and any other aspects of public interest, as described in **Recommendation N**.

Metrology

Recognising that results of measurements are the basic facts on which decisions are taken in conformity assessment and testing, as described in **Recommendation K**.

Agile/ flexible regulation

[DRAFT]

Recognising that the fast-moving, dynamic and sometimes uncertain pathways of AI Products, like any other emerging technologies, might require agile forms of governance and flexible regulatory approaches following the AI use cases rather than the AI technology itself in order to address regulatory concerns.

Gender-responsive

Reminding that the content and impact of standards for AI Products when implemented are gender responsive, as described in **Recommendation U**.

Product compliance

Stressing the importance of AI Product compliance as a key component of market surveillance and product enforcement framework, and its higher efficiency compared to post-market control in providing safety of consumers, society and environment, as well as for achieving fair market competition.

Legal requirements

[DRAFT]

Highlighting that management of AI Product non-compliance risk is of particular importance for setting priorities in market surveillance and import compliance with the purpose of removing dangerous and non-compliant products from the market, as described in **Recommendation V**.

Traceability & Validation

Highlighting that functional features and characteristics of AI Products with embedded digital technologies pose a greater challenge with additional demands on traceability and validation in regulatory compliance.

Horizontal digital frameworks

Sector-specific regulation

Highlighting the need for cross-sectoral regulatory AI Product impact assessments considering horizontal digital frameworks coinciding with sector-specific technical regulation.

Effective Risk management

[DRAFT]

Reminding that effective risk management is a necessary component of any regulatory system and that building risk-based regulatory systems that would be proportionate to AI Product risks that are relevant to the Sustainable Development Goals (SDGs) and targets is essential for sustainable development, as described in **Recommendation T**.

Sustainable development goals

Governments recognise Sustainable development as a UN cornerstone and consequently recognise to develop harmonized – cross-agency – criteria for the evaluation of AI Product non-compliance risk. Risk criteria for evaluation of non-compliance risks are based on the regulatory objectives, which take relevant SDGs into account, as described in **Recommendation T**.

Human-centric technology

Governments ensure that AI Products deploy human-centric technology and do not substitute human autonomy or assume the loss of individual freedom and primarily serve the needs of the people and the common good.

UN values & Fundamental rights

[DRAFT]

Governments ensure - in order to achieve a consistent and high level of protection of public interest with regards to health, product safety, fundamental rights and the UN values enshrined in the Universal Declaration and the UN Global Compact – that common normative standards for AI Products will be established. Those standards should be non-discriminatory and in line with international trade commitments.

Safety & security risks

Governments prevent and mitigate AI Product regulatory concerns by ensuring that only safe and otherwise compliant AI Products find their way into the market, given that safety and security risks may be generated by a product as a whole due to its digital components, including embedded digital technologies.

Reliable & accurate decisions

Governments ensure that in sectors where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and AI Products supporting human decisions should be reliable and accurate.

[DRAFT]

Protection as fundamental right

Governments consider the fundamental right to a level of protection of citizens, environment and sustainability when assessing the severity of the harm that AI Products can cause.

Children's rights

Governments consider children's vulnerabilities and provision of protection and care as necessary for their well-being with respect to AI Products and protect children specific rights as enshrined in the United Nations Convention on the Rights of the Child, further elaborated in the UNCRC General Comment No 25 as regards the digital environment.

Minimising digital divide

Governments recognise the needs of emerging economies in implementing digital technologies and related regulatory frameworks as part of National Quality Infrastructure and, as consequence, the necessity for capacity building and technical assistance in avoiding/minimizing a digital divide.

Complaints & Compensation

[DRAFT]

Governments provide natural and legal persons and groups of natural or legal persons with access to proportionate and effective remedies for harm caused by AI Product regulatory concerns. In particular, governments provide the right to lodge a complaint against the providers of AI Products and receive compensation against any direct damaged or loss they have with regard to their health, safety, or fundamental rights due to an infringement of their rights by the producer of AI Products.

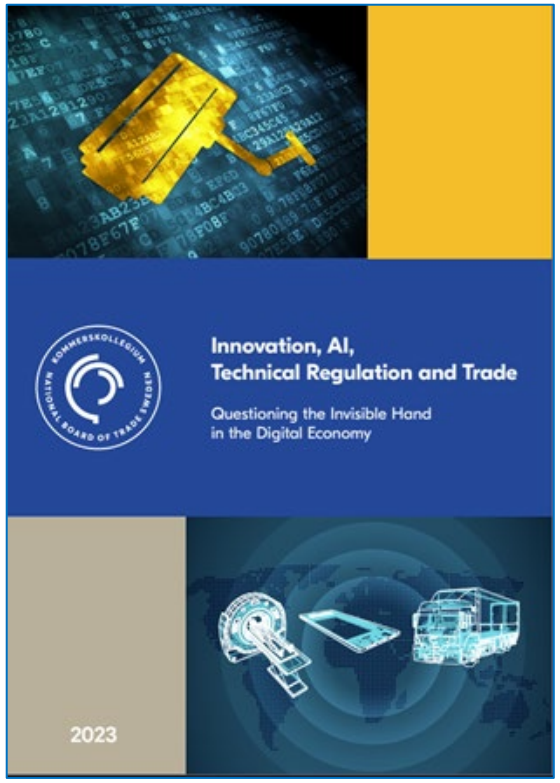
Border compliance

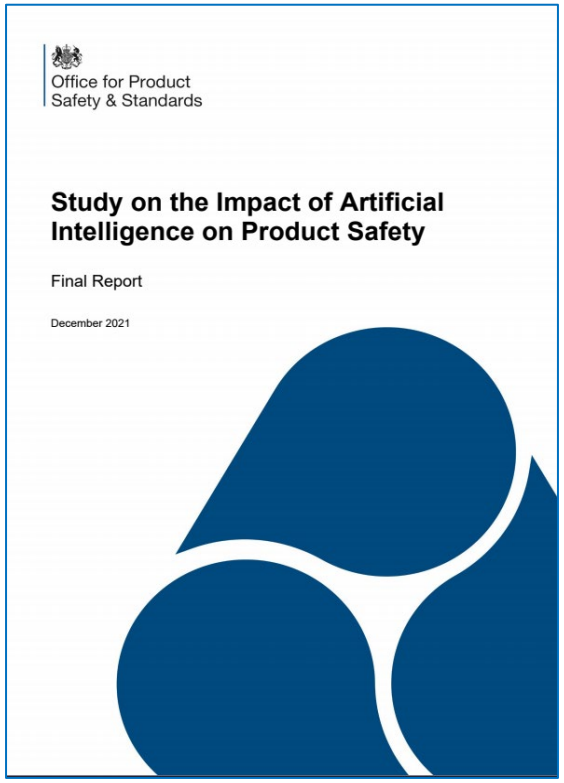
Product regulators develop and implement procedures necessary to explicitly address regulatory concerns of AI Products' non-compliance within their scope of responsibility, including within import compliance processes at the border, as described in **Recommendation V**.

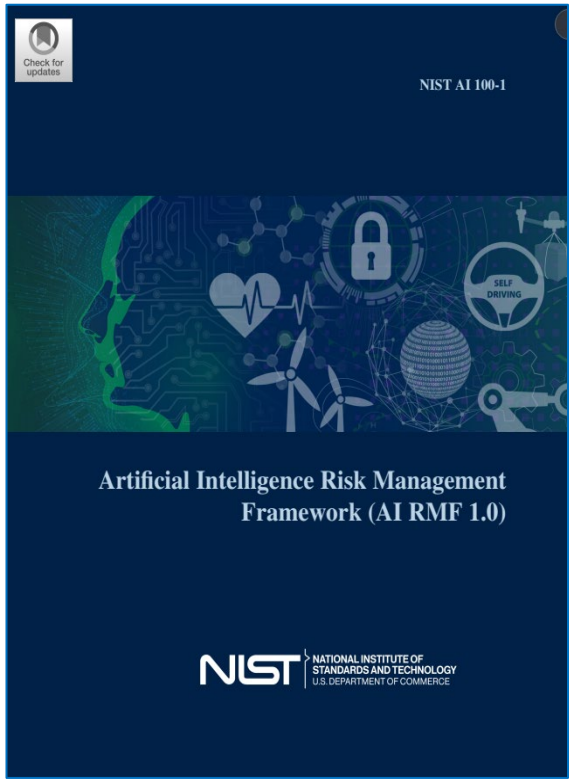
Customs & Trade disruption

Governments ensure that processes required for the management of AI Product non-compliance concerns are integrated into processes aimed at addressing customs-related and trade disruption risks.

Key documents (links in appendix 1)







Plus

- **ISO / IEC TR 24027** (“Bias in AI systems”)
- **ISO / IEC TR 24028** (“Trustworthiness of AI”)

Appendix 1 – References

- **REPORT: "Innovation, AI, Technical Regulation and Trade"**, Kommerskollegium – National Board of Trade Sweden, Website accessed 16 March 2023, https://www.kommerskollegium.se/globalassets/publikationer/rapporter/2023/innovation-ai-technical-regulation-and-trade-short-version.pdf

- **REPORT: "Study on the impact of artificial intelligence on Product safety"** – UK Office for Product Safety & Standards, Website accessed 16 March 2023, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1077630/impact-of-ai-on-product-safety.pdf

- **REPORT: "AI Risk Management Framework (Ai RMF 1.0)"** – US National Institute of Standards & Technology / Information Technology Laboratory, Website accessed 16 March 2023, https://doi.org/10.6028/NIST.AI.100-1

- **REPORT: "Model Rules on Impact Assessment of Algorithmic Decision-Making Systems Used by Public Administration"** – European Law Institute, Website accessed 16 March 2023, https://www.europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Model_Rules_on_Impact_Assessment_of_ADMSs_Used_by_Public_Administration.pdf

- **TECHNICAL REPORT: " ISO/IEC TR 24027:2021 / Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making"**, ISO, Website accessed 16 March 2023, https://www.iso.org/standard/77607.html

- **TECHNICAL REPORT:" ISO/IEC TR 24028:2020 / Information technology — Artificial intelligence (AI) — Overview of trustworthiness in artificial intelligence"**, ISO, Website accessed 16 March 2023, https://www.iso.org/standard/77607.html

- **OECD AI TOOL CATALOGUE: Human-Ai Paradigm for Ethics, Conduct & Risk (HAiPECR),** Website accessed 13 April 2023, https://oecd.ai/en/catalogue/tools/haipecr

Appendix 2 – Scope comparison

UN / UNECE WP.6 - AI Project

☑ **In scope**: the **compliance of products** which **integrate digital technologies** such as artificial intelligence.
☒ **Out of scope**: how AI and other technologies can be **used by administrations** in regulatory **processes**.

UN / UNECE WP.6 - Working Group

"The work of UNECE WP.6 in the area of Risk Management aims at

- developing **guidance** and **best practice (recommendations)**
- on how regulatory authorities can **establish regulatory frameworks**
- which effectively **manage the risks that confront consumers, citizens and communities.**"

Specifically, **UN / UNECE GRM** works on the following priorities:

- Risk Management in developing and implementing **technical regulations**
- **Standards** as risk management tools
- Risk Management in **Conformity Assessment**
- Risk Management in **Market Surveillance**
- Implementing the recommendations and best practice **at country level**
- Fostering the use of risk management tools in the context of the development and implementation of **sustainable development and resilience to disasters** (natural and man-made)

Source: https://unece.org/trade/wp6/thematic-areas/risk-management

Thank you.

Artificial intelligence

NeuroTech

Robotics

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