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WORKING PAPER

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Artificial Intelligence Act - PowerPoint Presentation : AI Act proposal: Article 6 and Annex II

Delegations will find in annex the PowerPoint Presentation on Artificial Intelligence Act made by the Commission at the Telecommunications and Information Society Working Party on 7 September 2021.

Proposal for an Artificial Intelligence Act

Article 6 and Annex II

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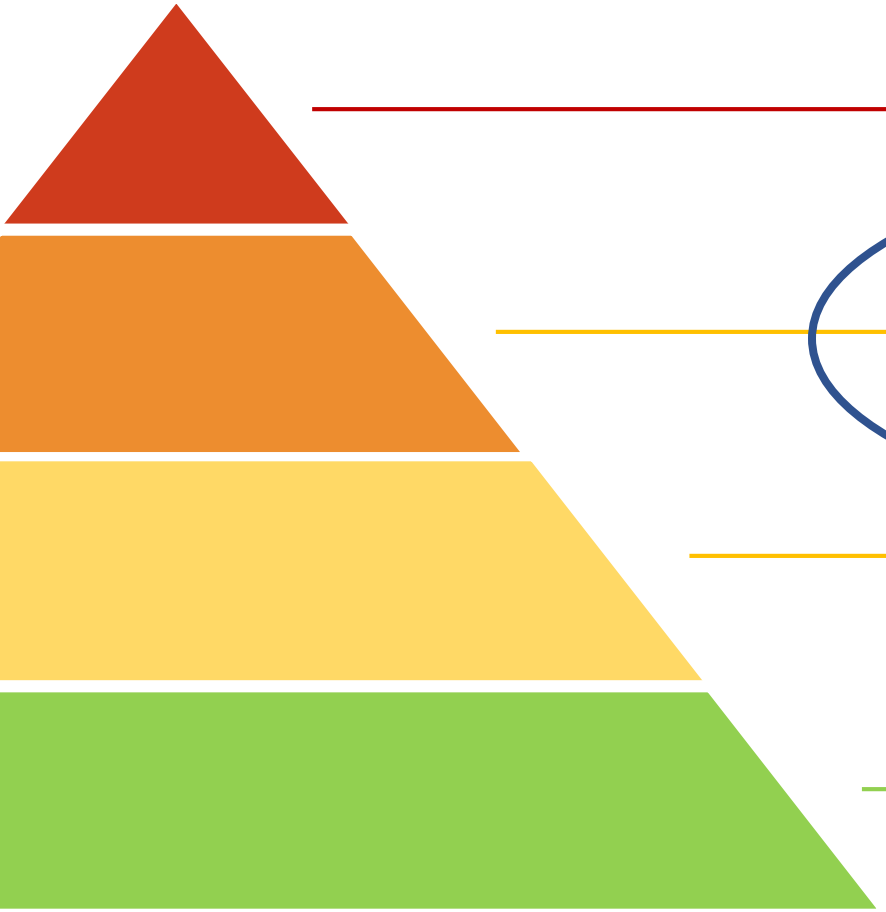
Background: Risk-based approach



Unacceptable risk
e.g. social scoring

Prohibited

High risk
e.g. recruitment, medical devices

Permitted subject to compliance with AI requirements and ex-ante conformity assessment

‘Transparency’ risk
‘Impersonation’ (bots)

Permitted but subject to information/transparency obligations

Minimal or no risk

Permitted with no restrictions

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Background: High-risk AI Systems

HIGH-RISK AI SYSTEMS IN AIA

1 **CERTAIN SAFETY COMPONENTS OF REGULATED PRODUCTS (OR CERTAIN AI SYSTEMS WHICH ARE PRODUCTS BY THEMSELVES)**

2 **CERTAIN (STAND-ALONE) AI SYSTEMS – SPECIFIC USE-CASES - IN THE FOLLOWING AREAS (ANNEX III)**

- ✓ Biometric identification and categorisation of natural persons
- ✓ Management and operation of critical infrastructure
- ✓ Education and vocational training
- ✓ Employment and workers management, access to self-employment
- ✓ Access to and enjoyment of essential private services and public services and benefits
- ✓ Law enforcement
- ✓ Migration, asylum and border control management
- ✓ Administration of justice and democratic processes

FOCUS OF ARTICLE 6

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Policy objectives of the Article 6 approach

- Focus on AI applications which have **an actual impact on safety** (and notably safety of products)
- **Take into full account well-established and extensive sectorial legislation** regulating many risky products (e.g. medical devices, cars, machinery)
- Ensure the **full integration of AI Act into the relevant sectorial legislation**, notably in terms of:
  - Alignment of relevant definitions (e.g. “safety component”);
  - Reliance on risk assessment of reference product in sectorial legislation (e.g. third-party assessment of reference product as a criterion for high level of risk);
  - Reliance on enforcement instrument of sectorial legislation (integration into existing conformity assessment)

CERTAIN SAFETY COMPONENTS OF REGULATED PRODUCTS (OR CERTAIN AI SYSTEMS WHICH ARE PRODUCTS BY THEMSELVES)

2 CUMULATIVE CONDITIONS (FOR BEING HIGH-RISK)

1. The AI system is intended to be used as a safety component of a product
OR
is itself a product

covered by the Union harmonisation legislation listed in Annex II

2. The product whose safety component is the AI system OR the AI system itself as a product

is required to undergo a third-party conformity assessment pursuant to the Union harmonisation legislation listed in Annex II.

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1ST CONDITION: AI SYSTEM AS A SAFETY COMPONENT OR PRODUCT BY ITSELF (1/3)

Safety component of a product

"a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property" (Article 3(14))

- Definition of "safety component"
  - Takes into account relevant precedents (notably definition of "safety component" in legal framework on machinery)

  BUT

  - It is adjusted to be more general and applicable across sectors (e.g. not limited to software being placed independently on the market)

1ST CONDITION: AI SYSTEM AS A SAFETY COMPONENT OR PRODUCT BY ITSELF (2/3)

AI system as a product by itself

- Reference necessary to capture any cases in sectorial legislation where independent software is considered as a product in itself
- Most **evident example** is independent medical device software, regulated by Regulation 745/2017 on medical devices

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

1ST CONDITION: AI SYSTEM AS A SAFETY COMPONENT OR PRODUCT BY ITSELF (3/3)

"Covered by the Union harmonisation legislation listed in Annex II" ("Covered" must be intended as referring to products)

Annex II includes **two distinct sets** of harmonization legislation"

1. **New Legislative Framework (NLF) Legislation -** Annex II, Section A -:

Main features: high-level requirements in law; tech solutions in harmonized standardization

- AI Act is an NLF-type framework
- It integrates smoothly listed NLF legislations (e.g same conformity assessment, notified bodies and market surveillance authorities)

2. **Other legislation** (based on **Old Approach** principles) – Annex II, Section B:

Main features: tech solutions in law or through IAs; stronger role for public bodies in pre-market approval

- Regulatory logics of AI and these legislations differ
- No direct applicability of the AI Act (except provisions on the review – Article 84)
- Targeted amendments (Title XII) ensure AI Act requirements will be taken into account when adopting future relevant IA/DAs under those legislations

Annex II – Overview of Legislation covered (1/4)

I. Section A - NLF-Legislation

1. *Dir. 2006/42/EC (as repealed by future Machinery Reg.) on* ***machinery***
   - *e.g. industrial machinery; sawing machines*

2. *Dir. 2009/48/EC on* ***safety of toys***
   - *e.g. baby dolls.*

3. *Dir. 2013/53/EU on* ***recreational craft/personal watercraft***
   - *e.g. watercraft intended for sports and leisure purposes*

4. *Dir. 2014/33/EU on* ***lifts*** *and safety components for lifts*
   - *e.g. elevator/lift for persons in a building.*

5. *Dir. 2014/34/EU on* ***equipment used in potentially explosive atmospheres (ATEX),***
   - *e.g. petrol pump/dispensers for petrol filling.*

6. *Dir. 2014/53/EU on* ***radio equipment***
   - *e.g. Satellite TV receivers (DVB-S).*

Annex II – Overview of Legislation covered (2/4)

I. Section A - NLF-Legislation

7.

Dir. 2014/68/EU on
pressure equipment
- *e.g. industrial pressure control valves in gas tubes.*

8.

Reg. (EU) 2016/424 on
cableway installations
- *e.g. mountain cableways for persons.*

9.

Reg. (EU) 2016/425 on
personal protective equipment
- *e.g. protective hearing devices.*

10.

Reg. (EU) 2016/426 on
appliances burning gaseous fuels
- *e.g. gas cooking stove.*

11.

Reg. (EU) 2017/745 on
medical devices
- *e.g. MRI scanner; diagnosis software; surgical robot*

12.

Reg. (EU) 2017/746 on
in vitro diagnostic medical devices
- *e.g. pregnancy tests; HIV tests*

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Annex II – Overview of Legislation covered (3/4)

II. Section B - Other Union Harmonization Legislation

1. Reg. (EC) 300/2008 on
common rules in the field of civil aviation security
- *e.g. airport security equipment*

2. Reg. (EU) 168/2013 on the
approval and market surveillance of two- or three-wheel vehicles and quadricycles
- *e.g. two- or three-wheel moped or motorcycle.*

3. Reg. (EU) 167/2013 on the
approval and market surveillance of agricultural and forestry vehicles
- *e.g. tractors, trailers, towed equipment.*

4. Dir. 2014/90/EU on
marine equipment
- *e.g. navigation equipment*

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Annex II – Overview of Legislation covered (4/4)

II. Section B - Other Union Harmonization Legislation

5.

Dir. (EU) 2016/797 on the
interoperability of the rail system

- *e.g. safety-critical components, involved in train movements.*

6.

Reg. (EU) 2018/858 on the
approval and market surveillance of motor vehicles and their trailers,
and of systems, components and separate technical units intended for such vehicles

- *e.g. cars and trailers.*

7.

Reg. (EU) 2018/1139 on
common rules in the field of civil aviation

- *e.g. civil drones; aircrafts*

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2ND CONDITION: PRODUCT SUBJECT TO THIRD-PARTY ASSESSMENT UNDER SECTORIAL LEGISLATION

- Product must be subject to "third-party conformity assessment pursuant to the Union harmonisation legislation listed in Annex II"
- Third-party must be intended as any party other than the producer/manufacturer (e.g. professional certification body/Notified Body, public body)
- Rationale of this 2nd condition: AI Act follows risk-based assessment of the product under sectorial legislation; under that legislation, third-party conformity assessment is considered as an indication that the product in question is high-risk

- **Special cases (e.g. toys)**: certain Union harmonisation legislation foresee that certain products may be exempted (opt-out) from third-party assessment if harmonised standards are in place and applied by the manufacturer
- Those products would still fulfil the 2nd condition of Article 6
- However, enforcement system of AIA adapted (See Article 43(3) 3rd subpara) – as long as applied harmonised standards also cover AI requirements, opt-out prerogative in sectorial law may be used for the AI system-part

Thank you