

EU regulatory requirements and intelligent machines

FIMA AfterWork: AI & Data Governance
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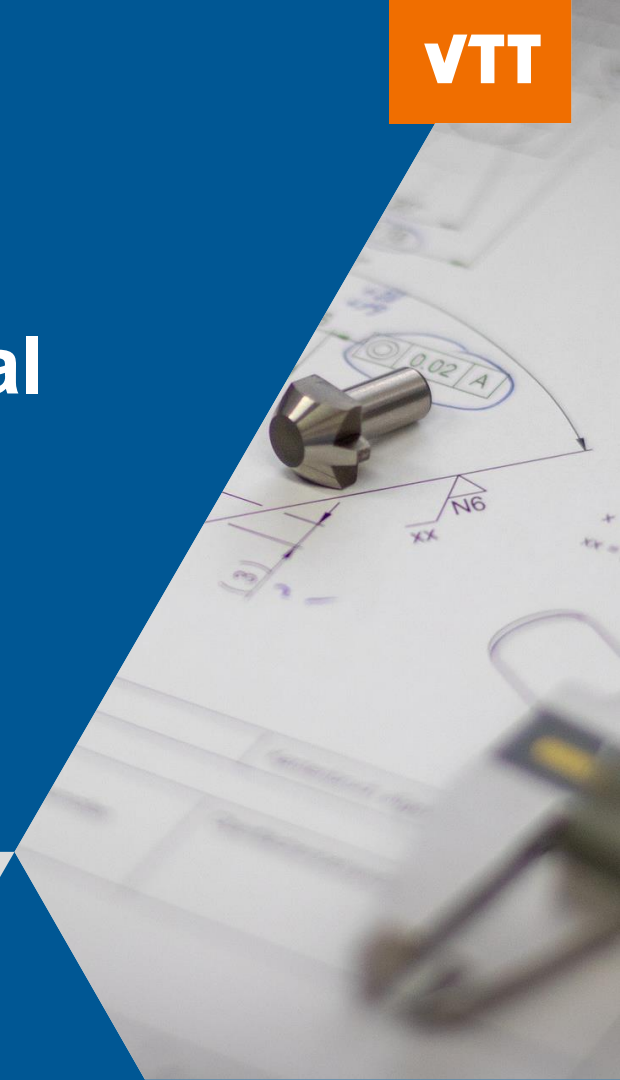
VTT – beyond the obvious

Introduction

- Two major regulatory developments ongoing at EU level:
 - Machinery Regulation (replacing the current machinery directive)
 - Artificial Intelligence Act
- Originally intended to be published simultaneously, but now AI Act seems to be lagging behind.
- Implications for machinery manufacturers?



Machinery Regulation proposal



Introduction

- Regulation (as opposed to directive)
- May be published already this year
- Comes into force after a transition period of 36 months from ratification



EUROPEAN COMMISSION

Brussels,
21.4.2021

COM(2021)
202 final

2021/0105(C
OD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL**

on machinery products

Changes compared to Machinery Directive & implications

- The list of high-risk machinery is expanded, and can be more dynamically adjusted in the future (Annex I in new regulation)
- Notable additions:
 - 24. Software ensuring safety functions, including AI systems.
 - 25. Machinery embedding AI systems ensuring safety functions.
- Software as safety component
- A notified body will have to be involved in conformity evaluations for high-risk machinery.
 - AI systems requires interaction with notified bodies, increased costs...

Changes compared to Machinery Directive & implications

- Cybersecurity considered (ref. to cybersecurity specific regulation).
- "Substantial modifications" considered.
- Autonomous mobile machinery considered.
 - "Autonomous mobile machinery products shall have a supervisory control function specific to the autonomous mode"

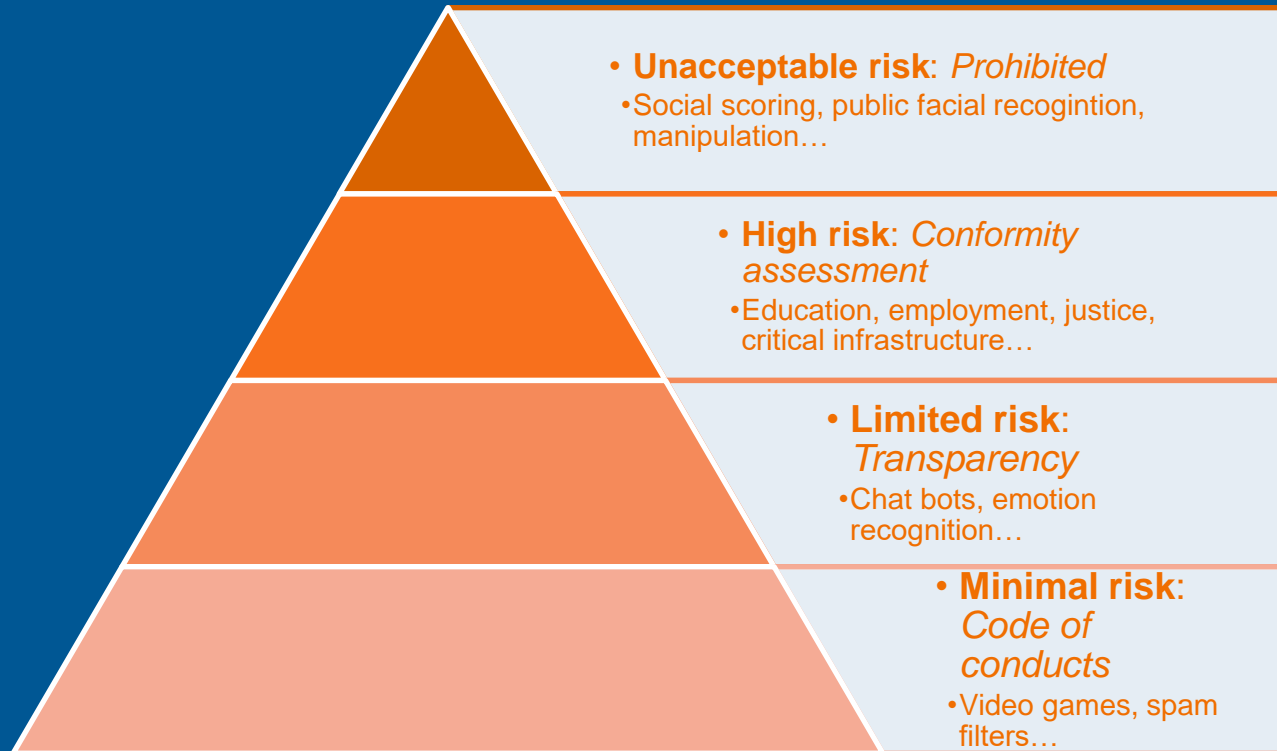
Artificial Intelligence Act proposal



EU Regulation: Artificial Intelligence Act

- Regulation proposal: Laying down harmonised rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts
- Definition of AI is wide!
 - *Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;*
 - *Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference/deductive engines, (symbolic) reasoning and expert systems;*
 - *Statistical approaches, Bayesian estimation, search and optimization methods.*

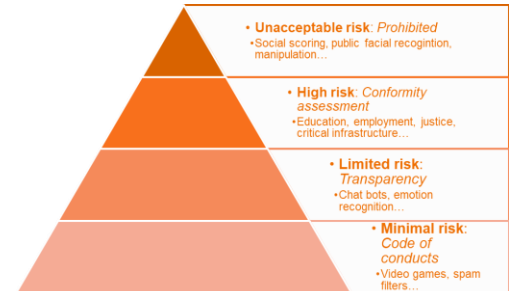
AI Act's hierarchy of risk levels



Unacceptable risk systems are prohibited

The following list of artificial intelligence practices are **prohibited** as contravening the Union values or violating fundamental rights protected under Union law:

- AI system that distort a person's behaviour, cause **physical or psychological harm**;
- AI system that **exploits vulnerabilities** of a specific group of persons; cause physical or psychological harm;
- AI systems for the evaluation or classification of the **trustworthiness** of natural persons
- AI for use of 'real-time' remote **biometric identification** systems in publicly accessible spaces (exceptions)



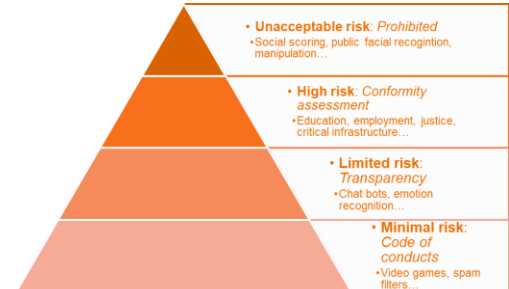
High risk systems

“AI systems intended to be used as safety component of products that are subject to third party ex-ante conformity assessment.”

Also:

Biometric identification and categorisation of natural persons:

(a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons

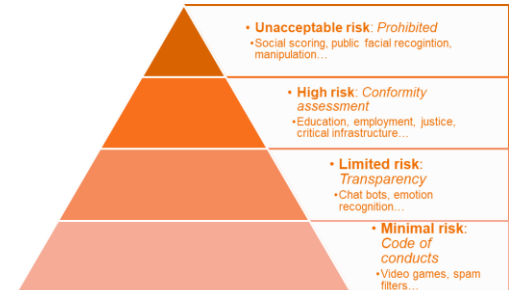


High risk systems

Some requirements:

- High-risk AI systems shall be designed and developed to ensure that their operation is sufficiently transparent to enable users to **understand and control how the high-risk AI** system produces its output.
- Quality and risk management systems

However, many statements are quite vague / unclear...



Conclusions

- The upcoming regulations heavily govern the use of AI technologies in machinery.
- Inconsistencies between the regulations due to the timing?
- Good to start preparing already now.

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