Yet another revolution grounded on tradition: regulating ‘new’ technologies by following a ‘tried-and-true’ product safety logic

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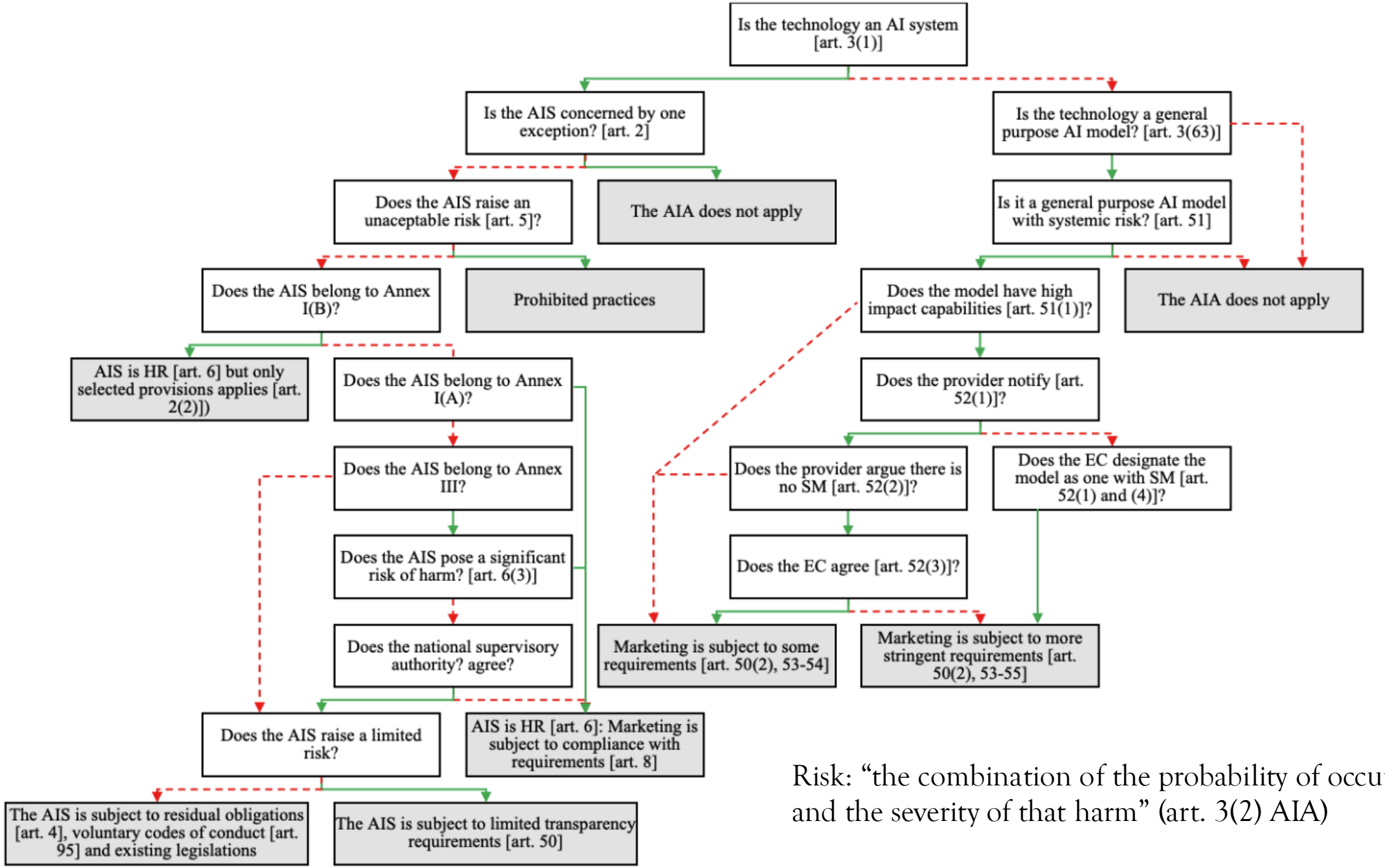
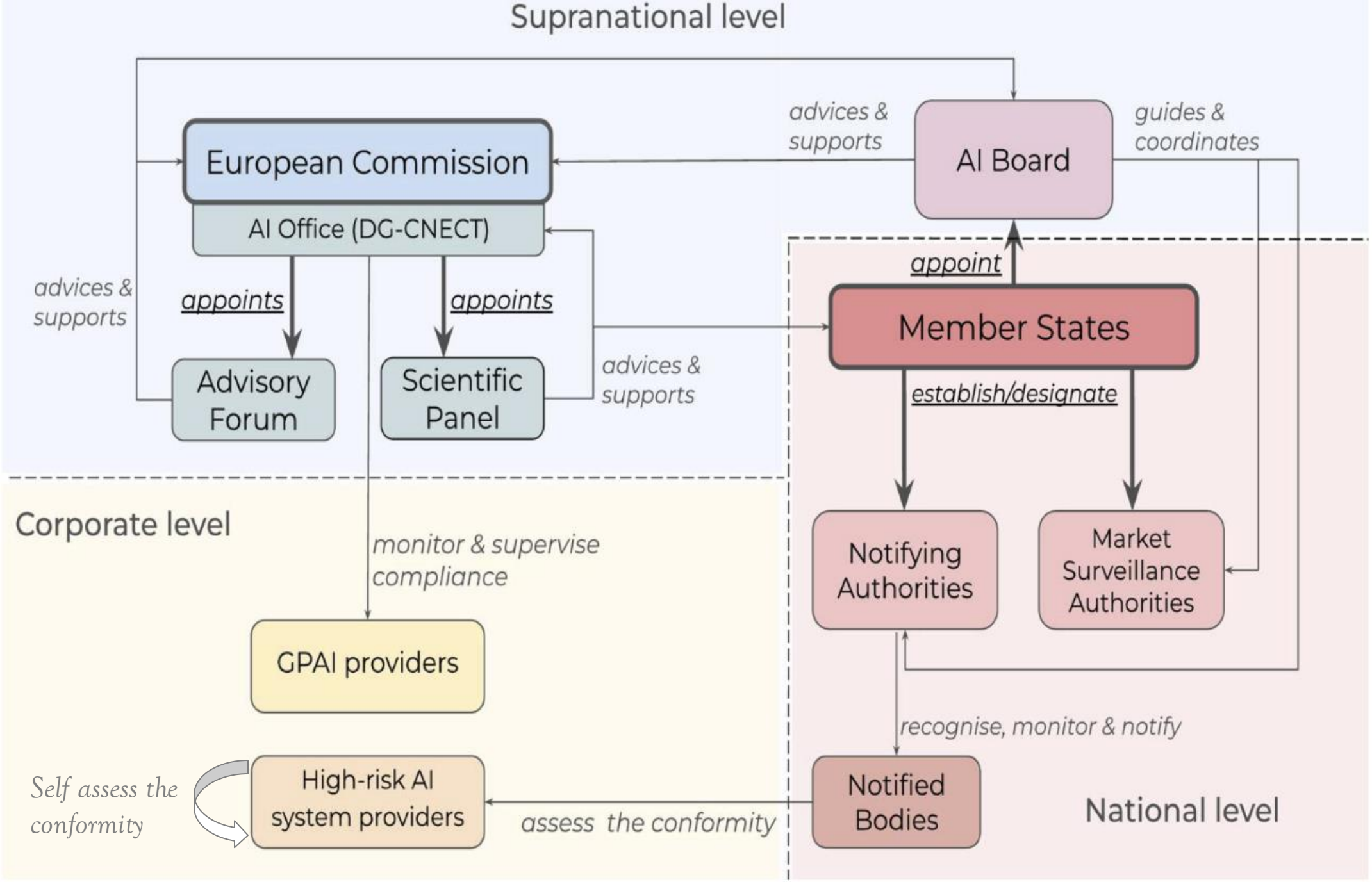
The AIA is part of the NLF



Risk: "the combination of the probability of occurrence of harm and the severity of that harm" (art. 3(2) AIA)

J. De Cooman, *The AI Act as a regulatory framework for technology: the rationales for regulation at the EU level revisited* (2024) https://hdl.handle.net/2268/319344



Adapted from C. Novelli et al., 'A Robust Governance for the AI Act: AI Office, AI Board, Scientific Panel, and National Authorities' (2024) *European Journal of Risk Regulation* 1-25

The New Legislative Framework

- The AI Act is part of EU product safety
  - Based on so-called New Legislative Framework (NLF)
    - EU legislature does not define technical specifications
    - EU legislature define essential requirements a product has to meet
- For a NLF product to be marketed within the EU, it has to be CE marked
  - High-risk AI systems does not escape the rule
- CE marking follows a twofold objective
  - It allows product to traded in the internal market without restrictions
  - It informs consumers that the product is (supposed to be) safe

CE Marking

- CE marking is up to manufacturers
  - AI providers:
    - Ensure their systems meet essential requirements (Art. 16(a) AIA)
    - Carry out conformity assessment (Art. 43 AIA)
    - Issue technical file (Art. 11 and 18 AIA)
    - Issue EU declaration of conformity (Art. 47 AIA)
    - Affix the CE mark to the product (Art. 48 AIA)

Conformity assessment

- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (recital 22):
  - "The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure"
  - "Conformity assessment should remain the obligation of the manufacturer alone."
- This sets the NLF apart from, *e.g.*, pharmaceutical regulations (Vos, 1999)
  - Where a public authority (EU medicine Agency) conducts an assessment before granting pre-marketing approval

Conformity assessment in the AI Act

- Providers of high-risk AI systems pursuant Annex I.A. have to follow the relevant conformity requirement under the relevant legal acts (art. 43(3) AIA)
  - *Caveat*: specific scope of application regarding high-risk AI systems pursuant Annex I.B (art. 2(2) AIA).
- Providers of high-risk AI systems pursuant Annex III have to follow the self-assessment procedure (art. 43(2) AIA)
  - Exception: providers of biometric AI systems (Annex III(1) AIA) who has applied either harmonised standards (art. 40) or common specifications (art. 41) can choose between self-assessment (Annex VI AIA) or the assessment by a notified body (Annex VIII)
    - Upshot: the assessment by a notified body is mandatory for biometric AI systems if harmonised standards or common specifications do not exist or were not applied by the provider (art. 43(1) AIA)
  - The provider may choose any notified body, except if it is put into service
    - by law enforcement, immigration, or asylum authorities --> data protection supervisory authority
    - by EU institutions, bodies, offices and agencies → European Data Protection Supervisor

The importance of standards in conformity assessment

- EU legislature sets the essential requirements
- Harmonised standards operationalise them
- In short:
  - The Commission issue a standardisation request to one of the three European Standardisation Organisations (ESOs)
    - European Committee for Standardisation (CEN)
    - European Committee for Electrotechnical Standardisation (CENELEC)
    - European Telecommunications Standards Institute (ETSI)
  - Chosen ESO drafts standards
  - Standards are published in the Official Journal of the EU

The importance of standards in conformity assessment

- In theory, harmonised standards are voluntary
- In practice, providers apply them
  - Presumption of conformity (art. 40(1) AIA)
- Upshot? The 'true' regulators of NLF products—including AI systems—are standardisation organisations (Vaele & Borgesius, 2021)

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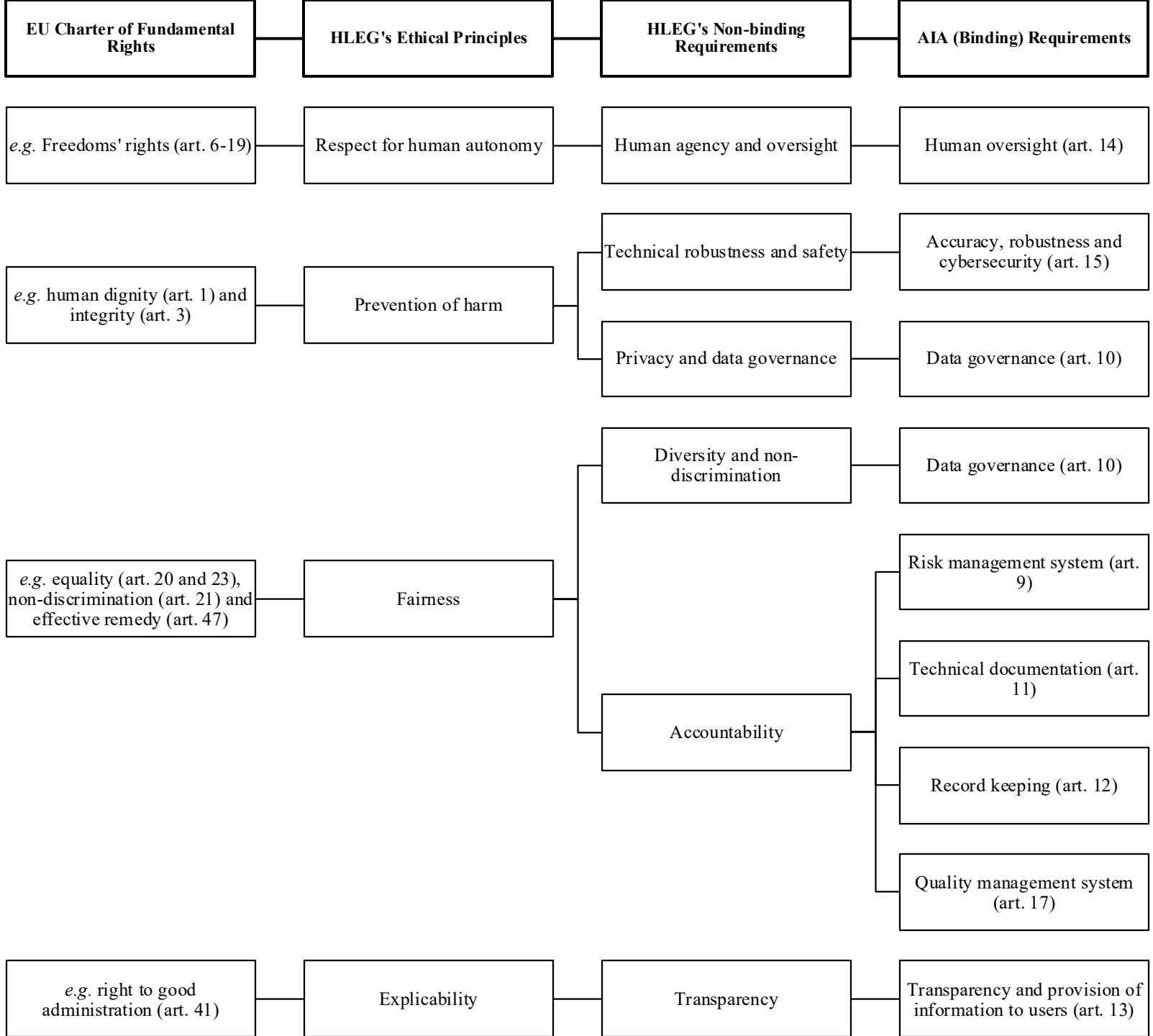
Harmonised standards and fundamental rights

Is there something new under the sun in the NLF?

- Toy Safety - Directive 2009/48/EU
- Transportable pressure equipment - Directive 2010/35/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Construction products - Regulation (EU) No 305/2011Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Non-automatic Weighing Instruments - Directive 2014/31/EU
- Measuring Instruments - Directive 2014/32/EU
- Lifts - Directive 2014/33/EU
- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU
- Marine Equipment - Directive 2014/90/EU
- Cableway installations - Regulation (EU) 2016/424
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746
- EU fertilising products – Regulation (EU) 2019/1009
- Drones - Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems
- Batteries - Regulation (EU) 2023/1542
- Machinery - Regulation (EU) 2023/1230
- Ecodesign requirements for sustainable products - Regulation (EU) 2024/1781
- **Artificial Intelligence Act - Regulation (EU) 2024/1689**
- Cyber Resilience Act - Regulation (EU) 2024/2847
- Packaging and Packaging Waste - Regulation (EU) 2025/40


EU Charter of Fundamental Rights
HLEG's Ethical Principles
HLEG's Non-binding Requirements
AIA (Binding) Requirements
e.g. Freedoms' rights (art. 6-19)
Respect for human autonomy
Human agency and oversight
Human oversight (art. 14)
e.g. human dignity (art. 1) and integrity (art. 3)
Prevention of harm
Technical robustness and safety
Accuracy, robustness and cybersecurity (art. 15)
Privacy and data governance
Data governance (art. 10)
e.g. equality (art. 20 and 23), non-discrimination (art. 21) and effective remedy (art. 47)
Fairness
Diversity and non-discrimination
Data governance (art. 10)
Accountability
Risk management system (art. 9)
Technical documentation (art. 11)
Record keeping (art. 12)
Quality management system (art. 17)
e.g. right to good administration (art. 41)
Explicability
Transparency
Transparency and provision of information to users (art. 13)

Risk of fundamental rights violation

- "The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex III by adding or modifying use-cases of high-risk AI systems where (…) the ***AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights***" (art. 7(1(b) AIA)
- "Deployers that are bodies governed by public law, or are private entities providing public services [except of they are deployers of 'critical infrastructure' AI system], and deployers of [AI systems intended to be used to evaluate the creditworthiness of natural persons] and [AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance], shall perform an ***assessment of the impact on fundamental rights*** that the use of such system may produce" (art. 27(1) AIA)

There is definitely something new under the sun

- This is the first time that the EU legislature tries to protect fundamental rights via harmonised standards
- Harmonised standards "incorporate core EU democratic values and interests, as well as green and social principles" (Commission, 2022)
- This raises three questions:
  - Is this surprising?
  - Is this problematic?
  - Is there a solution?

Is this surprising?

Merkel (2019)

"It will be the job of the next Commission to deliver something so that we have regulation similar to the ***General Data Protection Regulation*** that makes it clear that artificial intelligence serves humanity"

Von der Leyen (2020)

"AI that potentially interferes with people's rights have to be tested and certified before they reach our Single Market. This is a very simple question, because we do it just the same way with for example ***cars or chemicals, or cosmetics, or toys***"

Is this surprising?

- Regulation 1025/2012 organises harmonised standards:
  - "***Harmonised standard*** means a ***standard*** adopted by a ESOs" (art. 2(1)(c))
  - "***standards*** means a *technical specification*" (art. 2(1) in limine)
  - "*technical specification* means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down (…) the characteristics required of a product [or service] including levels of quality, performance, interoperability, environmental protection, health or safety" (art. 2(4)(a)-(c))
- Fundamental rights are not mentioned in Regulation 1025/2012

Is this surprising?

- The rules applicable to products that are part of the NLF are explained in the Commission Blue Guide (last version: 2022)
- "The New Legislative Framework now constitutes a complete system bringing together all the different elements that need to be dealt with in product safety legislation in a coherent, comprehensive legislative instrument that can be used across the board in all industrial sectors, and even beyond (***environmental and health policies also have recourse to a number of these elements***), whenever EU legislation is required."
  - Fundamental rights are not mentioned in the Blue Guide

Is this surprising?

- Regulation 2019/1020 on market surveillance and compliance of products
  - Market surveillance authorities "shall suspend the release of a product for free circulation if (…) it is established that (…) it presents a serious risk to health, safety, the environment or ***any other public interest referred to in Article 1.***"
  - "The objective of this Regulation is to improve the functioning of the internal market by strengthening the market surveillance of products covered by the *Union harmonisation legislation referred to in Article 2*, with a view to ensuring that only compliant products that fulfil requirements providing a high level of protection of ***public interests***, such as ***health and safety in general***, health and safety in the workplace, ***the protection of consumers, the protection of the environment and public security and any other public interests protected by*** *that legislation*, are made available on the Union market." (Article 1)
- Again, no reference to fundamental rights

Is this surprising?

- "***Standardisation*** should play a ***key role*** to provide technical solutions to providers to ensure compliance with this regulation, in line with the state of the art, ***to promote innovation as well as competitiveness and growth in the single market*** (Recital 121 AIA)"
- However:
  - "The common specification should be an exceptional fall back solution to facilitate the provider's obligation to comply with the requirements of this Regulation, when the standardisation request has not been accepted by any of the [ESOs]European standardisation organisations, or ***when the relevant harmonised standards insufficiently address fundamental rights concerns***" (Recital 121 + Art. 41(1)(a)(iii) AIA)
  - "The participants in the standardisation process shall ***seek to promote investment and innovation in AI***, including through increasing legal certainty, ***as well as the competitiveness and growth of the Union market***, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are ***consistent with Union values [and] fundamental rights***" (Art. 40(3) AIA)

Is this problematic?

- No necessarily, according to regulatory theory
  - Regulation *tout court* is the product of state actors
  - *Self*-regulation is the product of non-State actors
  - *Co*-regulation is the product of their cooperation (co-operation; co-production; co-regulation), *i.e.*:
    - Self-regulation where there is a "regulatory 'gorilla in the closet' that secure[s] its ultimate success" (Gunningham & Sinclair, 2017)
    - "A model that combines both legislation and self-regulatory instruments in support of the law" (Kamara, 2017)
    - "A regulatory framework that involves both private parties and governmental actors in the setting, implementation, or enforcement of regulatory standards" (Van Cleynenbreugel, 2021)
    - Meta-regulation: "activities occurring in a wider regulatory space, under the auspices of a variety of institutions, including the state, the private sector and the public interest group" (Grabosky, 2017)
    - Multisource regulation (Drahos & Kryger, 2017)

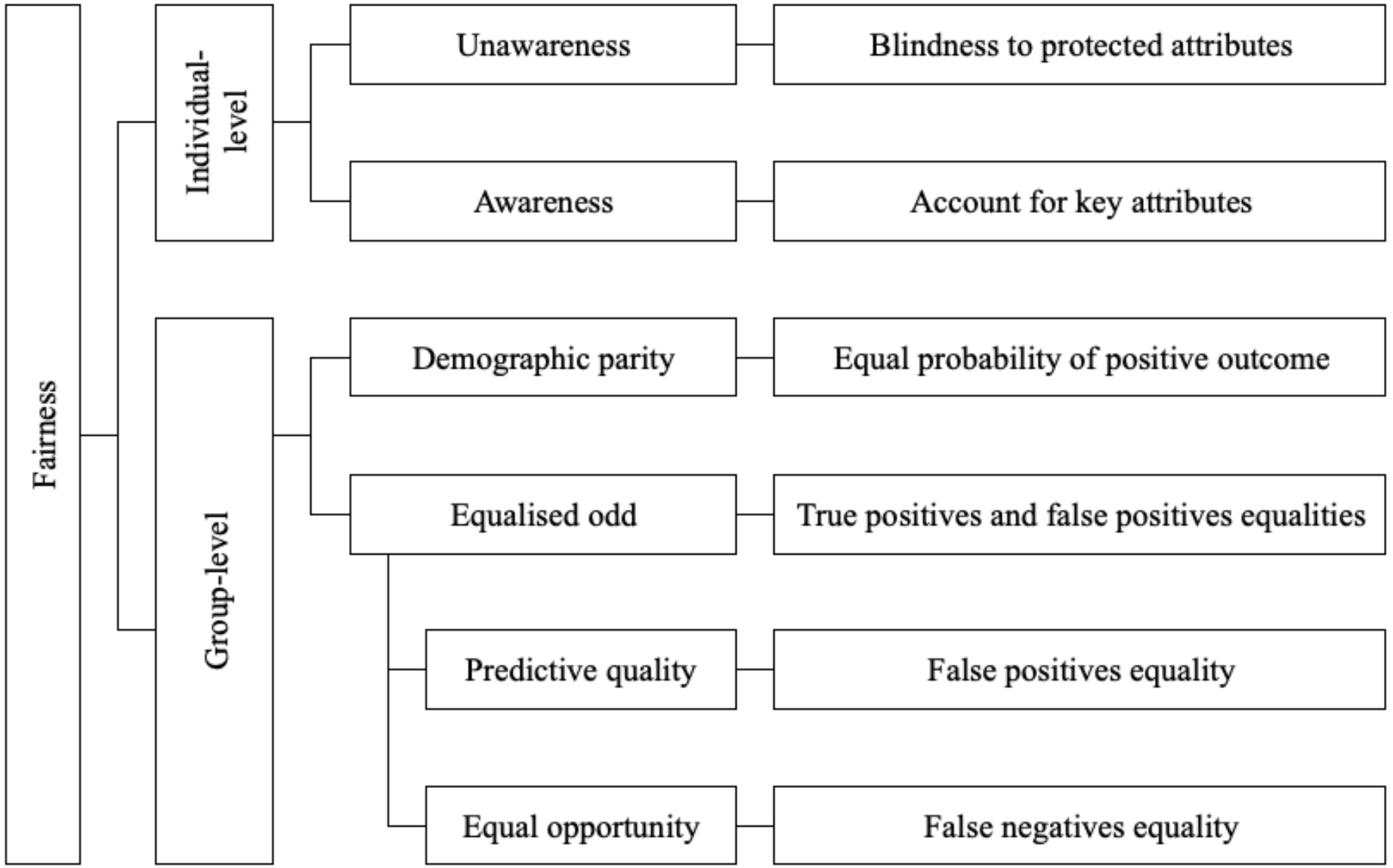
Is this problematic?

- No necessarily, according to regulatory theory:
  - Meta-regulation and co-regulation are forms of ***smart regulation*** (Gunningham and Sinclair, 2017):
    - "A form of regulatory pluralism that embraces ***flexible, imaginative and innovative forms of social control***"
    - "***The use of*** multiple rather than single policy instruments, and ***a broader range of regulatory actors***, will produce ***better regulation***"
  - The AIA is co-regulation / meta-regulation / smart regulation
    - EU legislature sets up essential requirements
    - ESOs operationalise them

Is this problematic?

- Yes, according to:
  - the European Association for the Coordination of Consumer Representation in Standardisation AISBL (in short, ANEC)
  - The 'legitimacy' scholarship
- Ideally, *normative* questions should be left to EU legislature and *technical* question should be left to ESOs (Laux 2024)
- Actually, "standards have politics" (Solow-Niederman 2024 // Wiener 1980)
  - Kranzberg's first law: "technology is neither good nor bad; nor is it neutral" (1986)
  - So do harmonised standards
    - E.g., fairness (see next slide)
    - Choosing one particular definition of fairness signals a preference for a specific logic and set of priorities (Gornet and Maxwell, 2024)

Is this problematic?



Is this problematic?

- In the *Seymour-Smith* case (C-167/97), the CJEU explained that, when statistics are available, the 'best approach' to compare them is to consider the respective proportions of advantaged group members who receive positive outcomes and those with negative ones compare those proportions with those of disadvantaged groups.
- Demographic disparity: a system would in theory be fair if the difference in the probability of favourable results between the disadvantaged and the advantaged groups is equal to 0.
- In practice, a small (positive or negative) difference can still be considered fair (the closer to 0, the greater the fairness).
- No threshold set by the CJEU

Is this problematic?

- Question:
  - What makes providers the "best place to carry out complete conformity assessment procedure" when it comes to fundamental rights (*cf.* 768/2008/EC)?
  - Is standardisation effective?
    - Yes, when it comes to interoperability, cross-border services, and switch-costs reduction (e.g., telecommunication standards)
    - Not always, when it comes to health and safety standards
      - EU law requires medical grade silicon for breast implant
      - Breast implant (industrial silicon) CE certified by German notified body
      - 40,000 affected women in France; 400,000 worldwide
    - Probably not, when it comes to fundamental rights
      - Doubtful CEN (or ISO) and CENELEC (or IEC) have relevant expertise in the area of fundamental rights

Is there a solution?

- What standards can do:
  - **Product-based standards**: define and identify relevant and workable tools or measures known in the literature
    - E.g., ISO/IEC TR 24027:2021 "provides mitigation techniques that can be applied throughout the AI system life cycle in order to treat unwanted bias"

ISO/IEC TR 24027:2021(en) Information technology

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Is there a solution?

- What standards can do:
  - **Procedure-based standards** (*i.e.*, standards that guide how a company should structure its internal systems)
    - *E.g.*, CEN JT021019 "competence requirements for AI ethicists professionals" (under drafting):
    - "This document provides a ***systematized framework for the competencies of AI ethicists***, categorizing them into knowledge, skills, and attitudes related to the specific activities and tasks of the role. It ***identifies requirements and recommendations necessary for individuals to effectively perform as AI ethicists***. These competencies encompass a strong understanding of European values and fundamental rights, further enhancing the knowledge, skills, and attitudes required for this profession. ***The document aims to foster a shared understanding of the essential concepts and principles inherent to the AI ethicist role***. It illustrates a clear, uniform approach to the integral components of this profession. Moreover, the document outlines how the role of AI ethicists can be seamlessly integrated into a wide variety of organizations. These include, but are not limited to, commercial enterprises, government agencies, and non-profit organizations."

Is there a solution?

- What standards cannot do:
  - EC's request concerns Chapter III, Section 2, AIA
    - Includes article 9 (risk management system)
      - Standards can define how to conduct a risk assessment system (i.e., details what elements it should contain)
      - Standards cannot determine what "residual risk (…) is judged to be acceptable" (art. 9(5) AIA)
        - A standard cannot determine what type of risk is acceptable or not
      - Standards cannot organise trade-off between, *e.g.*, fairness and performance (but can provide different different definitions and ways of measuring fairness)
        - "The technical documentation referred to in Article 11(1) shall contain (…) a detailed description of the elements of the AI system and of the process for its development, including (…) the decisions about possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Chapter III, Section 2" (Annex IV(2)(b)).

Is there a solution?

- **Quality** standards (aka **performance** standards; Blind, 2004):
  - Usual in product safety (*e.g.*, what materials are to be used)
    - ISO 3506-5:2022(en)—Fasteners: "The properties of stainless steel and nickel alloy fasteners for high temperature applications result from the chemical composition of the material, from the heat treatment process and from the manufacturing process of the fasteners. Static or dynamic properties at room temperature like tensile strength, hardness or fatigue resistance are not sufficient enough to design fasteners for high temperature applications properly.
    - In fact, at high temperatures e.g. above 300 °C, additional phenomena occur, for instance:
      - decrease in tensile properties and hardness,
      - hot oxidation and scaling,
      - stress relaxation,
      - creep.
    - All these phenomena significantly affect the durability and service life of fasteners. Therefore:
      - a proper choice of material grade is essential to avoid heavy hot oxidation,
      - qualification of fasteners through dedicated tests should be performed."

Is there a solution?

- **Quality** standards (aka **performance** standards; Blind, 2004):
  - Usual in product safety
  - But
    - "nearly impossible to establish for AI systems due to their probabilistic nature, which makes their reaction to certain tests ***highly dependent on the situation***, the data on which the system has been trained, etc." (Gornet and Maxwell, 2024)
    - Such standards would require setting a threshold for *e.g.*, acceptable level of fairness and, hence, acceptable level of discrimination
      - Above (or below) that threshold, the AI system would be 'fair enough'
    - Harmonised standards should neither make value-laden judgement nor answer normative questions (Laux et al. 2014)

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Conclusion

Conclusion

- The EU AI Regulation is part of the NLF
  - It is surprising
  - It is not necessarily problematic
    - Harmonised threshold-based standards cannot be set for the protection of fundamental rights
      - It is not up to standardisation organisations to define what an acceptable level of protection to fundamental rights is (i.e., to define which system is 'fair enough')
    - ESOs should be invited to develop harmonised standards which disseminate good practices (how to design risk management pursuant art. 9 AIA), or means of disclosures (what the technical disclosure pursuant art. 11 AIA should contain), but not define the acceptable residual risk or the appropriate trade-off to be made between, e.g., fairness and performance
  - Under these conditions, the AIA—as part of the NLF—will deserve to be labelled a ***smart*** regulation

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