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AI in Business and Society

Dec 11th, 12:00 AM

A Review of Challenges and Critiques of the European Artificial Intelligence Act (AIA)

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Completed Research Paper

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Abstract

The Information Systems (IS) research community has been interested in Artificial Intelligence (AI) for many years. The European Commission proposed the European Artificial Intelligence Act (AIA) in April 2021 with the goal of providing a harmonized regulatory framework for the development and deployment of AI technology. The AIA is a unique initiative which holds great significance for IS research and practice. Although the Act has gained significant attention, research has highlighted various challenges and critiques. This systematic literature review categorizes and summarizes existing AIA research to identify these issues, which primarily pertain to the regulation's formulation, compliance, enforcement, and anticipated impacts on industry and civil society. We suggest future IS research directions, focusing on compliance with regulation, formulation of legal regulation, and longitudinal research covering multiple policy cycle stages.

Keywords: Artificial Intelligence, Regulation, AI Act, Ambiguity, Compliance, Policy cycle

Introduction

Artificial Intelligence (AI) has rapidly transformed various aspects of our lives, such as communication, work, and even our thought processes (Cukier and Mayer-Schoenberger, 2013; Wang and Siau, 2019). The development and deployment of AI systems that can learn and make decisions independently raise critical concerns about accountability and transparency (Teodorescu et al., 2021). In recent years, Information Systems (IS) research has been heavily engaged with AI themes (Ågerfalk et al., 2022). The *MIS Quarterly* special issue on managing AI (Berente et al., 2021), the *JAIS* special issue on AI in organizations (Benbya et al., 2021), and the special issues on responsible AI in *Information Systems Frontiers* (Dennehy et al., 2023) and the *Scandinavian Journal of Information Systems* (Vassilakopoulou et al., 2022) serve as notable examples of AI research efforts in the field of IS.

The complexity and potential risks of AI make it essential to establish regulatory frameworks to ensure responsible and ethical development and use of AI aligned with societal values. The European Commission proposed the European Artificial Intelligence Act (AIA) in April 2021 as the first European Union (EU)-wide legal framework on AI. The AIA is a horizontal regulation that, once adopted, will cover AI applications across all sectors in the EU. It classifies AI systems into four risk levels, ranging from unacceptable risk systems the use of which is forbidden (e.g., social scoring by governments or real-time biometric identification in public), over high-risk systems to limited- and minimal-risk systems. In the AIA, companies that provide AI systems are referred to as providers, and those who deploy AI systems are

referred to as users. Different requirements for the development/provision and professional use of systems are set based on the risk category. While low-risk AI systems have minimal requirements of transparency, high-risk systems are more heavily regulated with requirements for transparency, human oversight, testing, documentation, data quality and governance, and robustness, accuracy, and security.[1] After the European Council reached a common position in December 2022, the European Parliament adopted its negotiating position in June 2023. Trialogue negotiations between the Council and Parliament are expected to take place from June to late 2023. In terms of the process for public policymaking, the "policy cycle" (Howlett and Giest, 2012), the AIA is currently in the regulation formulation stage. The decision to adopt the AIA is expected late 2023 or early 2024. In the implementation stage of the policy cycle, providers and professional users of AI would need to start complying with the AIA.

IS researchers now have a unique opportunity to engage with AI regulation. A recent *MIS Quarterly* editorial identified the AIA as a significant issue for IS research (Burton-Jones et al., 2023, p. iv). Engaging with EU-level AI regulation is in line with the IS field's turn beyond the organizational boundaries to address societal implications and grand challenges (Levy et al., 2020; Winter et al., 2014). Bailey and Barley (2020) call to extend the IS research scope beyond design and use, toward issues of ideology, power, and institutions. The IS community is turning its attention increasingly towards concerns of regulation (Lindman et al., 2023) and compliance (Dickhaut et al., 2023). In the *Society for Information Management's* (SIM) annual IT executive surveys, the subject of "Compliance and Regulations" climbed from the 16th most important topic in 2013 to the fourth in 2022, as reported by Johnson et al. (2023).

Collins et al. (2021) requested research on how regulators can keep pace with AI development, and the AIA represents an attempt by the regulators to do just that. While the AIA is undoubtedly a significant topic of interest for the IS community, it has also piqued the interest of various other research disciplines such as law, political science, computer science, management, and more. The number of research articles that address the AIA is steadily increasing. Earlier research has already emphasized that the regulation of AI is complex (Almeida et al., 2020). The AIA presents a possibility to enhance our understanding of these challenges in the context of the EU's inaugural legal framework on AI. It also serves as a guide to identifying pertinent areas for AI regulation focused IS research. Against this background, we conducted a systematic literature review which was guided by two interrelated research questions: 1) *What are the critiques of the AI Act according to research*; 2) *What challenges exist in regulating AI based on these critiques*?

Our paper proceeds as follows. First, we summarize prior IS research on legal regulation, and then describe our research method. We summarize the findings of our literature review and discuss our findings to provide directions for future IS research on legal regulation and the AIA.

Earlier IS research on legal regulation

IS research has examined legal regulations from many perspectives across different industries and practical contexts. Our own literature review focuses on the AIA that is currently in the middle of its policy process to become law in Europe. To structure our summary of some earlier IS literature on legal regulation, we utilize the policy cycle, a process model on public policymaking (Howlett and Giest, 2012). The policy cycle includes the stages of agenda setting, policy formulation, decision-making, implementation, and evaluation in public policymaking.[2] In this section, we summarize key perspectives from previous empirical IS research related to regulation. This review is illustrative, not exhaustive.

The largest body of IS research on regulation has focused on the **implementation stage of the policy cycle**, which refers to the execution and enforcement of the regulation (Howlett and Giest, 2012). We distinguish two IS sub-streams. One sub-stream has considered the ***enforcement of and compliance with regulation***. Aguiar et al. (2018), for example, investigate the effect of an enforcement of online copyright law in Germany in the context of shutting down the unlicenced video streaming platform kino.to, and the effect that media coverage about the shutdown has had on online piracy rates. Hui et al. (2017)

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[1] For a brief overview of the AIA and requirements set in the AIA, see: https://www.ceps.eu/wp-content/uploads/2021/04/AI-Presentation-CEPS-Webinar-L.-Sioli-23.4.21.pdf (accessed 29.08.23)

[2] Public policy "has an authoritative, legally coercive quality that the policies of private organizations do not have" (Anderson 2013, p. 9). Legally binding regulations are typical outcomes of public policymaking.

studied the impact that the enforcement of the Convention on Cybercrime had on deterring distributed denial of service attack. Currie et al. (2018) investigated in-depth how regulatory change impacted the socio-technical compliance environment inside financial organizations, with a focus on the role of regulatory technology when organizations try to meet regulatory and compliance requirements. Currie and Seddon (2022) show how technology instantiates financial regulation, where regulators "impose stringent compliance practices on financial organizations by embedding formal rules and regulations in the software" (p. 31). Butler (2011) view "green IT/IS" as a way for organizations to achieve compliance with obligations from such regulations that "focus on the direct effects of Green IT throughout the product life cycle" (p. 10) and which affect the production, performance, and design of a wide range of IT artefacts. Kim et al. (2022), in contrast, conceptualize the disclosure of patient health information as a prosocial rule breaking behaviour, which is a violation of laws and regulations such as the Health Insurance Portability and Accountability Act. Some studies that investigate compliance with regulation also address or problematize the (formulation of) legal requirements set in a regulation. Drummer and Neumann (2020) point towards the disparity between IT capabilities and legal requirements in the context of smart contracts that have been enabled by blockchain technology. Grundstrom et al. (2019) investigated how European insurance companies made sense of the General Data Protection Regulation (GDPR) and pointed towards challenges with complying to these requirements from the viewpoint of personal data access. Väyrynen and Lanamäki (2020) illustrated how different technological solutions could be interpreted as having or lacking regulative legitimacy within the context of an ambiguously formulated taximeter regulation.

Another sub-stream of IS research has focused on the ***impact of regulation on industries, organizations, and individuals***. Cooper et al. (2017) studied high-frequency trading in financial markets, considering how regulatory changes affected the way traders operate. Focusing on the industry-level, Steinhauser et al. (2020) investigated organizational versus regulatory drivers of discontinuous innovation adoption in telemedicine and found that digital complementary assets have a greater effect on this than regulation. Monteiro and Macdonald (1996) studied how the airline industry in the United States changed after the 1978 Deregulation Act, finding that deregulation led to a more strategic use of information in the industry. The impact of regulation on organizations has also received broad attention. For example, Khan and Lacity (2014) looked at how organizations respond to pressures against offshoring, discovering that organizations are less responsive when executives perceive more regulatory uncertainty. Hu et al. (2016) examined firms' green IT practices and discovered that government regulations influenced industry norms, a company's internal readiness, and competitors' green practices. In a study on individual-level, Watson et al. (2019) investigated the effectiveness of constraint mechanisms for information systems in different countries. They found that clients in Saudi Arabia and China favoured legal constraints, whereas clients in the US preferred social constraints.

Some IS studies focus on the **evaluation stage of the policy cycle**, where the effects of a regulation are evaluated in terms of the intended outcomes and unintended consequences (Howlett and Giest, 2012). Chan et al. (2019), e.g., investigated the effect that Section 230 of the Communications Decency Act, which "shields websites from liability for unlawful postings by third parties" (p. 219), on Craigslist becoming a place for prostitution ads and its contribution to increased prostitution. Slivko and Andres (2021) investigated the effects of the German Network Enforcement Act had on content generation on Twitter.

Overall, most IS research on regulation seems to focus on the implementation stage of the policy cycle and the evaluation of legal regulation outcomes. The agenda-setting, policy formulation, and the decision-making stages receive less attention, despite their immense impact on the technology development and use.

Research Methods

Data collection. To gain a wide overview of the discussions revolving around the AIA, we conducted a discipline-agnostic systematic literature review that captures all relevant peer-reviewed English-language research on the AIA. We conducted a literature search on 26 September 2022 involving five scientific databases: Scopus, IEEE Xplore, ACM Digital Library, EBSCOHost, and AIS e-Library. Along the PRISMA guidelines (Moher et al., 2009), we first identified the articles using two search terms: "AI Act" and "Artificial Intelligence Act". This stage brought us 143 relevant papers. We then recognized that some relevant articles did not use these terms but instead talked about the "Act on Artificial Intelligence." We then did the search again with these search terms on 9 October 2022, and found 6 additional articles. 149 articles were imported into Covidence for screening, and 45 duplicates were removed. Next, the remaining

104 documents were screened based on the article titles and abstracts by two authors, 30 studies were excluded as irrelevant. Reasons for exclusion included: non-peer-reviewed articles, language not English, proceedings' introduction, and trend/industry analysis. A total of 74 articles passed into full text assessment of eligibility. At this stage, 25 articles were excluded if the full-texts language was other than English (2 articles), the full article was not accessible to us (5 articles), the article was not a research article/peer-reviewed (5 articles), or they only mention the AIA without addressing it more specifically (13 articles). We chose articles which point out challenges and critique the AIA, and thus the results reflect the more negative discourses. Finally, 49 studies were included in our analysis. They are marked in the list of references with an asterisk. Figure 1 summarizes our literature review process.

Figure 1. Adapted PRISMA Diagram of the Literature Review Process
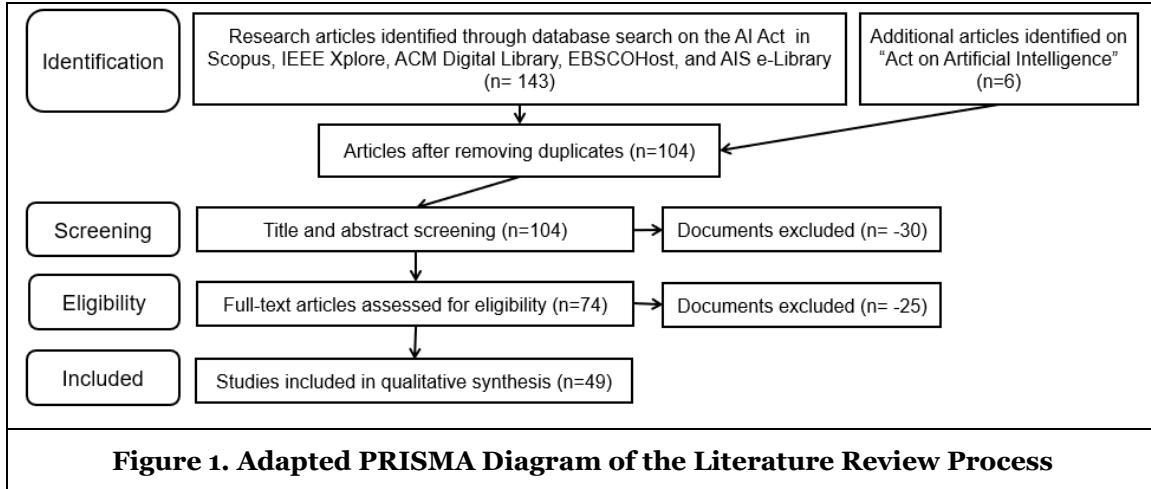
Data analysis. For each article, we identified critique or challenges related to the AIA. We looked for mentions of problems, challenges, unclarities, or uncertainties. This part was mostly done by one author. Next, all authors together discussed and coded the identified sections of 24 articles into different themes to gain a common understanding of the types of challenges and critiques. One author coded the rest of the sections and formulated descriptions of each code. Those were reviewed by the other authors and negotiated together. The codes at this stage included: *premise or approach; scope; wording or formulation; other regulation; limited guidance; requirements; compliance; enforcement;* and *impact*. In the next step, one author took those coded themes and analysed in more detail what the critique is about, which stakeholders are mentioned (system providers, system users, those affected by the system use, etc.), and how they may be impacted by the AIA. A number of more fine-grained challenges and critiques were identified, which the author team together arranged into three broader themes that these critiques and challenges related to: 1) the regulation, which encompasses critique and challenges related to the AIA and its alignment with other regulations; 2) compliance-related critique and challenges of the AIA for system providers and system users and challenges of enforcement; and 3) expected impact of the AIA. The Findings are arranged according to these themes. We present here a very condensed summary of the findings and ask the reader to refer to the original sources to read more about the context/details of the critique and challenges.

Findings

Regulation

Premise and approach of the AIA. The AIA's *aim to regulate non-existent, future technology* is predicted to impede innovation (Oprea et al., 2011). The AIAs *approach* has been labelled as techno-centric and seen to reinforce dependency on system providers (Helberger and Diakopoulos, 2022), company-centric because it ignores end users (van Kolfschooten, 2022), but also as human-centric and ignoring the environment (Pagallo et al., 2022). The risk-based approach is expected to divert attention from creating public value and leaving many AI systems unregulated, potentially impacting fundamental rights (Helberger and Diakopoulos, 2022; Stuurman and Lachaud, 2022). The concept of 'intended purpose' in the AIA is also criticised with arguments that potential uses of the system post a bigger concern. It is not uncommon for products to serve purposes other than those intended by the seller (Raposo, 2022).

Scope of the AIA. The *broad scope* of the AIA is problematic. The definition of AI may encompass much related to everyday data processing (Linkeviciute et al., 2022), resulting in an overly inclusive scope where the only common factor in regulated systems may be data processing (Mökander et al., 2022a). Consequently, it can be difficult to find programmes not fitting the description of AI systems (Schwemer and Pasini, 2021). The scope of the AIA has faced critique for its limitations. These include a heavy focus on software at the expense of hardware (Raposo, 2022), overlooking relevant use cases and user organizations (Barkane, 2022), and neglecting *sector specific use of AI systems*. The AIA does not cover use of AI systems in law enforcement (Roksandic et al., 2022), the electricity sector (Niet et al., 2021), healthcare (van Kolfschooten, 2022), or the public sector (Fink and Finck, 2022). It lacks support for innovation and legal mechanisms for AI use in research (Raposo, 2022). However, the logic of regulating different sectors with different restrictions, such as the public sector, is unclear (Veale and Zuiverdeen Borgesius, 2021). Another concern related to the scope is *who is considered in the AIA*. Critics point out that the AIA's emphasis on system providers, its lack of obligations for users, and the absence of rights for those affected by AI systems pose issues (Fink and Finck, 2022; Hacker and Passoth, 2022; Helberger and Diakopoulos, 2022; Orlando, 2022; van Kolfschooten, 2022). The absence of established rights for legal action against AI system providers or compensation mechanisms raises accountability concerns (Raposo, 2022). The AIA does not consider choices made in the development phase (de Matos Pinto, 2021) or the non-expert (Hacker and Passoth, 2022). The role of professional users is limited, and a lack of consideration of use and the use context is thought to imply that societal problems related to AI can be solved in design (Helberger and Diakopoulos, 2022). The scope of 'small-scale providers' do not include small and medium-sized enterprises (Tomada, 2022). The AIA scope determines that the *bar for unacceptable AI is high*. As physical or psychological damage must be caused, the severity of potential harm from data leaks is not acknowledged. AI applications may use sensitive data in healthcare, but this has not been considered high-risk in the AIA. (van Kolfschooten, 2022). The AIA does not consider immaterial harm (de Matos Pinto, 2021), privacy (van Kolfschooten, 2022), societal harm, or harm towards time and autonomy caused by manipulation (Franklin et al., 2022), nor sustainability and the environment (de Matos Pinto, 2021; Kindylidi and Cabral, 2021; Pagallo et al., 2022). The AIA has potential gaps in its bans on manipulation and facial recognition, as some scenarios fall outside the definitions (Raposo, 2022). The *risk-based approach* also affects the scope. Within the high-risk category, there is no differentiation between different levels of high-risk systems (Roksandic et al., 2022), and non-high risk AI systems receive limited regulatory attention (Varošanec, 2022). Requirements are only set for high-risk AI (Orlando, 2022). Systems not classified as high-risk have few rules for compliance, but they can indirectly affect people (Roksandic et al., 2022). These systems rely on 'soft law' instruments such as codes of conduct even though they can cause harm (Varošanec, 2022). For example, accounting falls outside the high-risk category (Oprea et al., 2011).

Formulation and wording of the AIA. The *wording and formulation of the AIA is ambiguous*. This results in uncertainty whether a specific AI system is subject to the AIA and which risk category. The AIA can be interpreted in many ways (Ludvigsen et al., 2022), partly due to missing or problematic *definitions of key concepts*. The definition of AI is a point of contention. Some expect the broad definition to result in unwanted consequences (Linkeviciute et al., 2022). The terminology is compared to the US Algorithmic Accountability Act, which has been proposed to be adopted in the AIA (Mökander et al., 2022b). There seem to be legal problems with the definition of AI autonomy, which recognizes AI systems based on inputs by humans and the ability to generate outputs with some autonomy (Orlando, 2022). The AI definition also lacks distinctions between data and algorithms (Raposo, 2022). When the definition of an AI system is unclear, it raises the question whether the AIA applies to an AI system or not (Linkeviciute et al., 2022).

Legal certainty is negatively impacted by missing definitions, non-specific terminologies, and ambiguities (Bertolini and Carli, 2022). Key concepts missing a definition include "use", "put into service" (Svantesson, 2022); "right to a reasoned decision" (Fink and Finck, 2022); "fundamental rights", "non-discrimination", "risk" (Langenbucher and Corcoran, 2021); "manipulation" and "subliminal practices" (Bertolini and Carli, 2022). Meanings and definitions may depend on the context, as is the case with requirement for datasets to be relevant, representative, free of error, and complete (Lorch et al., 2022). Defining concepts such as "emotional data" in the legal context is complex, e.g., because biometric data can become emotional data (Gremsl and Hödl, 2022), and the definition of emotion recognition does not recognize the use of biometric data (Czarnocki, 2021). Moreover, the distinction between product, system, service, and performance can be critical for product liability but e.g., in robotic surgery making a clear distinction seems impossible (Guerra, 2021). The AIA's wording is sometimes too vague to ensure the targeted use of AI systems. For

example, biometric surveillance systems can be utilized in ways that should be prohibited (Barkane, 2022). The high-risk areas of administration of justice and democratic processes also introduce significant legal uncertainty (Schwemer and Pasini, 2021). The definitions in the AIA can also be problematic. The definition of user and provider is focused on market placement of AI systems (not development of the systems), and this may cause legal uncertainty regarding liability and accountability (de Matos Pinto, 2021).

The AIA was criticized for a *lack of guidance*. These are practical questions, such as: how can affected persons review and contest outputs of AI systems (Hacker and Passoth, 2022); what follows from detection of bias in training data (Hacker, 2021a); and how much information should be provided about automated risk assessment models used in decision making (Pesch et al., 2022). The requirement to provide reasons behind decision-making raises questions about the content, nature, and depth of AI explanations (Fink and Finck, 2022). In the AIA, high-risk AI systems must be transparent enough for users to be able to interpret the system output, and users must have access to use instructions that details the information about the characteristics, capabilities, and limitations of the AI system (Bordt et al., 2022). The scope of explanations is unclear in the level of communication, language, and presentation when someone is subjected to emotion recognition or biometric categorisation systems (Stuurman and Lachaud, 2022). It is unclear which algorithms are considered explainable and what are suitable post-hoc explainability methods (explanations after the model is trained) for different audiences, such as non-experts (Gevaert, 2022). In healthcare, it is not clear when patients must be informed of use of AI systems in medical decision-making (van Kolfschooten, 2022). Quantitative risk assessment systems face challenges because there is no standard method to assess their performance. The AIA expects users to detect and address bias, but this can be challenging when data is unavailable, and fairness can have conflicting definitions. Consequently, evaluating high-risk systems without clear guidance is difficult (van Dijck, 2022).

In many cases, *the criteria or thresholds* for application in specific contexts, technologies, or techniques remain unclear. It is unclear which models can be considered interpretable (Gevaert, 2022), or what is "sufficient transparency" (Varošanec, 2022). The requirement for sufficient transparency is seen as an opportunity for black-box models (Lorch et al., 2022). Uncertainties also revolve around what is "individual use" and what counts as a system "leading to" an outcome (Veale and Zuiverdeen Borgesius, 2021); what "statistical approaches" entail (Schwemer and Pasini, 2021); what constitutes subliminal techniques, who are considered vulnerable individuals, and what is considered significant harm (Franklin et al., 2022). The applicability of the AIA is unclear when an individual is not sufficiently identifiable in data (Hacker, 2021b). The criteria for discrimination and bias are not defined, and the 'non-discrimination' term that is used in the AIA is vague (Lim et al., 2022). It is unclear when algorithms that replicate existing biases might cross the threshold of discrimination (Lütz, 2022). Examination of datasets for biases is required, but the meaning of these properties depends on context and application (Lorch et al., 2022). Vague formulation creates *uncertainty for technologies and techniques*. Differentiating between high-risk and non-high-risk systems allows for interpretation (Schwemer and Pasini, 2021). For example, determining when a recommender system qualifies as high-risk depends on its impact, making risk classification complex (Hildebrandt, 2022). There is also uncertainty about the use of facial datasets for non-commercial purposes because the definition of 'non-commercial' is unclear (Hupont et al., 2022). Emotional AI attempts to objectify humans for specific purposes raise concerns. Such endeavors may treat humans as objects, a particularly worrisome issue in cases where AI systems are intended as lie detectors for law enforcement authorities. Such applications raise concerns about human dignity, emphasizing the importance of treating humans as subjects rather than objects (Gremsl and Hödl, 2022).

The *role of different actors related to the AIA is unclear*. The proposal lacks definitions of regulatory sandboxes and the European AI Board (Voss, 2021). The AIA includes a European AI Board as a regulatory body with representation for the commission, member states, European Data protection supervisor, and sub-groups for specified questions. This Board has faced critique for excluding stakeholder groups, lacking a defined organizational structure, and failing to specify its tasks (Stahl et al., 2022). Another actor-related issue is the delegation of risk assessment powers to the Commission to update the list of AI systems (de Matos Pinto, 2021). The AIA requirement for member states to create "national competent authorities" with supervisory, notifying, and market surveillance authority to ensure application of the AIA is deemed ambiguous (Voss, 2021). It is uncertain how the proposed regulatory sandboxes will operate, potentially discouraging companies from participating (Tomada, 2022). It is uncertain whether AI systems operating within the sandbox are subject to regulation (Raposo, 2022).

Requirements of the AIA. The *requirements for AI system providers* have raised critique. Trusting companies to self-assess compliance is problematic because it is unreliable and creates opportunities for misuse (Varošanec, 2022). The obligation for non-EU companies to appoint a representative can be burdensome, raising questions about scalability, cost, its impact on both developed and developing countries, and the international legal basis for this jurisdiction (Svantesson, 2022). The AIA has also been criticised for its *lack of requirements for users of AI systems*. It does not require AI users to explain or justify their decisions to those affected by them or provide the rights for individuals to make demands or objections (Fink and Finck, 2022; Mökander et al., 2022a; van Kolfschooten, 2022). Some argue that responsibility should be based on the level of control stakeholders have over the system. Designers exert significant control, while end-users share some responsibility (Helberger and Diakopoulos, 2022). The AIA also lacks requirements to ensure explainability or quality (Bordt et al., 2022; Gevaert, 2022).

Compatibility and alignment with the existing regulatory landscape. The AIA is criticized for not contributing to existing legislation or regulation, such as disclosure obligations (Hacker and Passoth, 2022). Moreover, the AIA can conflict or be inconsistent with other regulations or laws (de Gregorio and Dunn, 2022; Hacker, 2021a; Konttila and Väyrynen, 2022), such as general non-discrimination laws (Hacker, 2021a), or intellectual property rights (Raposo, 2022). The potential impacts of overlapping regulations on conformity assessment remain uncertain, and conflicts between EU regulatory standards are expected (Raposo, 2022). AI based healthcare technology is subject to ambiguity from existing regulations, which may be increased by the AIA (Konttila and Väyrynen, 2022). Moreover, the trustworthy AI policy does not align with the conceptualization of trust with human dignity and autonomy that is elemental in patients' rights (van Kolfschooten, 2022). The AIA's premise of citizens benefiting from AI systems without harm is not in line with the EU vehicle safety regulation that sees human-state measurements and emotion profiling as risky (McStay and Urquhart, 2022). Double regulation can also be a challenge in public decision-making (Varošanec, 2022). The requirement for non-EU companies to appoint a representative raises questions, including what would happen if other major AI markets made the same demand. Such "regulatory web" would be difficult and costly to manage (Svantesson, 2022).

Compliance with and enforcement of the AIA

Compliance of AI system providers. The requirements in the AIA have been criticised for being *unrealistic and impossible to comply with*, particularly when considering all EU regulation together (Raposo, 2022). The AIA's requirements of completeness and freedom from errors in data are criticised as utopian, and particularly unlikely to be fully achieved in large AI training datasets (Hacker, 2021a, Raposo, 2022). Also, verifying the representativeness, completeness, and correctness of used datasets in natural language processing is declared impossible (Schwemer and Pasini, 2021). *Assigning responsibility* according to the EU liability model can be a challenge. For example, in machine learning we can see that components can be designed and produced by many different actors, so it is difficult to say who is liable (Guerra, 2021). Another issue is the *lack of standards* for compliance assessment and enforcement (de Matos Pinto, 2021; Simbeck, 2022) and standards or protocols for the requirement of risk management and testing AI (Lorch et al., 2022). A challenge is how *existing approaches or techniques in the industry* can conform to the requirements of the AIA. Current post-hoc explainable AI approaches cannot provide reliable explanations for every prediction (Lorch et al., 2022). An underlying challenge in compliance is also the unclarity in *how expectations should be interpreted*, such as the AIA requirement of explainability in high-risk AI applications (Bordt et al., 2022). System providers can *exploit the uncertainties and legal ambiguity* in the regulation. For instance, if a robot manipulates emotions and designers intentionally select features to influence emotions, the providers may argue that the manipulation is "under control" (Bertolini and Carli, 2022). In this way, they can claim compliance based on the AIA's wording.

Compliance of AI system users. For the professional users of AI systems, *different contexts* have their own challenges. A challenge for assigning responsibility is identified in the institutional, organisational, and societal contexts of AI systems (Helberger and Diakopoulos, 2022). In clinical research, the risk classification creates uncertainty because the risk level depends on how and why the AI tools are used (Linkeviciute et al., 2022). As for explainability, it is a challenge to determine which algorithms are interpretable for different audiences (Gevaert, 2022). Another example is relying on knowledge bases where it is unclear whether they are considered a part of the training set and thus subject to regulation (Schwemer and Pasini, 2021). In the public sector, there is uncertainty in defining liability in algorithm based ranking services (de Matos Pinto, 2021). *Use of technologies or techniques* can be problematic, e.g., foundation

models and general-purpose models have issues of accuracy and bias (Wójcik, 2022), and use of biometric recognition has social and ethical implications (de Matos Pinto, 2021). A challenge for the requirement of accuracy, robustness, and cybersecurity in forensic image analysis stems from access restrictions, unexpected manipulations, and external conditions such as dirt covering a lens (Lorch et al., 2022). AI system *users can exploit the ambiguities and legal uncertainty* in the AIA. One can argue that there is no need to disclose the logic of profiling models if the final decision is made by a human (Pesch et al., 2022). As the quality of explainability is not guaranteed (Bordt et al., 2022), it could lead to abuse by system providers (Varošanec, 2022). There is also a risk that a human supervisor will rely on the decision made by AI, which has implications for accountability, liability, and transparency (Orlando, 2022).

Enforcement of the AIA. Enforcing the AIA may be *challenging*. It lacks safeguards to uphold the integrity of voluntary codes of conduct of non-high-risk AI system providers, making it harder to enforce AIA requirements (Mökander et al., 2022a). Entrusting providers with self-assessment is seen as a disadvantage, and there are concerns regarding how fundamental rights will be protected during conformity assessments by notified bodies (Raposo, 2022). Transparency self-assessment may reduce pressure to enforce the regulation, resulting in weak compliance (Hacker and Passoth, 2022). Compliance with representative localisation may be costly for foreign companies, and the lack of enforcement would benefit non-compliant companies (Svantesson, 2022). There are still questions around *who will decide*, e.g., whether an AI system's output is appropriate (Varošanec, 2022), what the risk level of an AI system is (Raposo, 2022), and the enforcement of responsibility for autonomously operating AI systems (Panattoni, 2021). Challenges may also arise in jurisdictions due to AI's involvement in administrative, civil, and criminal issues, not to mention the regulatory bodies and authorities established under the AIA or by national authorities (Raposo, 2022).

Expected impact of the AIA

The AIA faces critique for its expected impacts. It is deemed inadequate in addressing technological challenges (Bertolini and Carli, 2022). Moreover, Lim et al. (2022) argue that legal means alone cannot fully control risks. Critique also arises regarding how the AIA will *impact liability* and accountability (de Matos Pinto, 2021; Orlando, 2022). The AIA's limitations in regulating liability aspects are problematic, especially if they are not covered by other regulations, as relying solely on national law may lead to fragmentation (Martín-Casals, 2022).

Expected impact for industry. *Unwanted impact for industry* is the AIA creating barriers for system providers or users. The broad definition of AI is expected to have a negative impact on innovation, investment, and legal certainty, leading to increased costs and administrative requirements (Linkeviciute et al., 2022). This potential hindrance to innovation is acknowledged in the health technology sector (Konttila and Väyrynen, 2022). Compliance requirements are likely to be a barrier for small-scale providers, as the focus is on development rather than deployment or implementation (Tomada, 2022). This regulation may also result in inefficiencies if providers are held liable for violations related to training data, even if the output meets the required quality standards (Hacker, 2021a). Allowing AI providers to self-regulate may create imbalances in information and power (Varošanec, 2022). In computational law, the AIA's ambiguity may lead to injustice and delays in identifying and resolving financial harm (Ludvigsen et al., 2022).

Expected impact for civil society. *Unwanted impact of the AIA for citizens* is its perceived lack of impact. The provisions within the AIA are expected to fall short of its stated goals (Veale and Zuiverdeen Borgesius, 2021). There is uncertainty about whether the transparency requirements can protect consumers (Helberger and Diakopoulos, 2022) and whether they are sufficient for citizens (Varošanec, 2022). Questions arise about the AIA's ability to empower end-users or those affected with the rights to protect themselves, especially since providers can self-assess their compliance (Hacker and Passoth, 2022; van Kolfschooten, 2022). Furthermore, the AIA does not provide grounds for those affected by AI systems to hold regulators accountable and challenge regulatory decisions (Veale and Zuiverdeen Borgesius, 2021). Not placing the responsibility of protecting patients' rights to the EU member states is considered a flaw in the AIA, and its impact may be a "legal vacuum" in patients' rights (van Kolfschooten, 2022). The AIA's wide scope could limit national efforts to address the societal effects of AI systems (Veale and Zuiverdeen Borgesius, 2021).

Discussion

We make two contributions with our research. Our **first contribution is to highlight the challenges related to regulating AI**, as discussed in the 'Findings' section. Although our findings are mainly based on research on the April 2021 draft of the AIA, we believe they remain relevant for subsequent versions of the Act. We summarize our findings in Figure 2. Please note that Figure 2 provides less detail on the theme of regulation due to the numerous challenges and critiques identified. For our findings regarding AIA compliance and its expected impact, we've provided more detailed insights. We've identified three broad areas of challenges and concerns related to the AIA: (1) Concerns about the regulation itself; (2) Challenges and concerns related to AIA compliance for organizations who provide AI and organizations who professionally use AI in contexts classified as high-risk in the AIA, along with AIA enforcement; and (3) Critiques and concerns related to the expected impact of the AIA, foremost on industries and civil society. In top of the Figure 2, we have placed our findings within the context of the policy cycle for public policymaking (Howlett & Giest, 2012). We argue that the challenges and critiques that we identified as being related to the *regulation* (i.e., the AIA) foremost relate to the stages of agenda setting, policy formulation, and decision-making in public policymaking. These stages involve defining regulation's premise and approach, the scope, and formulations, and compliance requirements. It is also where the alignment with existing or anticipated future regulation is considered. While some challenges are specific to AI system providers or professional users, others apply to both groups, as depicted in Figure 2. In contrast, we argue that the challenges and critiques we have identified concerning AIA *compliance and enforcement* and its *expected impact* are mainly related to the policy implementation stage (policy execution and enforcement) (Howlett and Giest, 2012) and the evaluation stage. The evaluation stage assesses the regulation's effects in terms of intended outcomes and unintended consequences in the context of public policymaking.

As our **second contribution, we identify and discuss new potential areas for IS research on legal regulation**. While current IS research has heavily focused on studying regulation-related phenomena in the context of the implementation (see Section "Earlier IS research on legal regulation"), it has largely neglected the agenda-setting, policy formulation, and decision-making stages of public policymaking. Against this background, our identification of challenges and critique related to different stages in the public policy cycle opens suggestions for research on the already established IS stream on compliance with and enforcement of regulation, and on the evaluation of regulation, but also suggestions for new and yet unexplored areas for IS research on the AIA and legal regulation more generally. We acknowledge that some of the challenges we identified are not only AIA specific but are also relevant for other European-level regulation, such as the lack of accepted standards at the time when a regulation is being formulated, or how to ensure that new regulation fits into the "landscape" of already exiting and other regulations "in-the-making". Although our review points towards numerous important topics that IS scholars are involved in and that are expected to be of importance in the context of the AIA, such as regulatory sandboxes, risk assessments, and auditing, due to length restrictions we focus here on discussing three of the most promising directions in more detail and present suggestions for more specific, exemplary research questions within these themes in Table 1. Research questions proposed in Table 1 are linked to the background or justifications for asking these questions with "[Q#]" in the text below.

IS research has already acknowledged compliance with and enforcement and impact of legal regulation on the industry, organizations, and individuals as important research topics (e.g., Currie et al., 2018; Currie and Seddon, 2022; Butler, 2011; Väyrynen and Lanamäki, 2020). The IS discipline also has in recent years been increasingly focused on AI-related themes (e.g., Ågerfalk et al., 2022; Berente et al., 2021; Benbya et al., 2021). The AIA provides an exciting opportunity to merge these streams to study legal regulation in the context of AI, a technology with a quite unique nature and an ever-increasing role in society.

Our review highlights the important theme of (challenges related to) compliance with regulation in the context of AI development and professional use of AI: a lack of standards, uncertainty in compliance, and unrealistic requirements raise concerns. IS research and practice has increasingly acknowledged the importance of legal compliance (Johnson et al., 2023). A potentially fruitful direction for future IS research would be "lawfulness by design" (Dickhaut et al., 2023) as a way for organizations that develop (high-risk) AI systems to ensure compliance with the AIA.

Figure 2. Challenges and Critiques of the AIA Identified in Prior Research
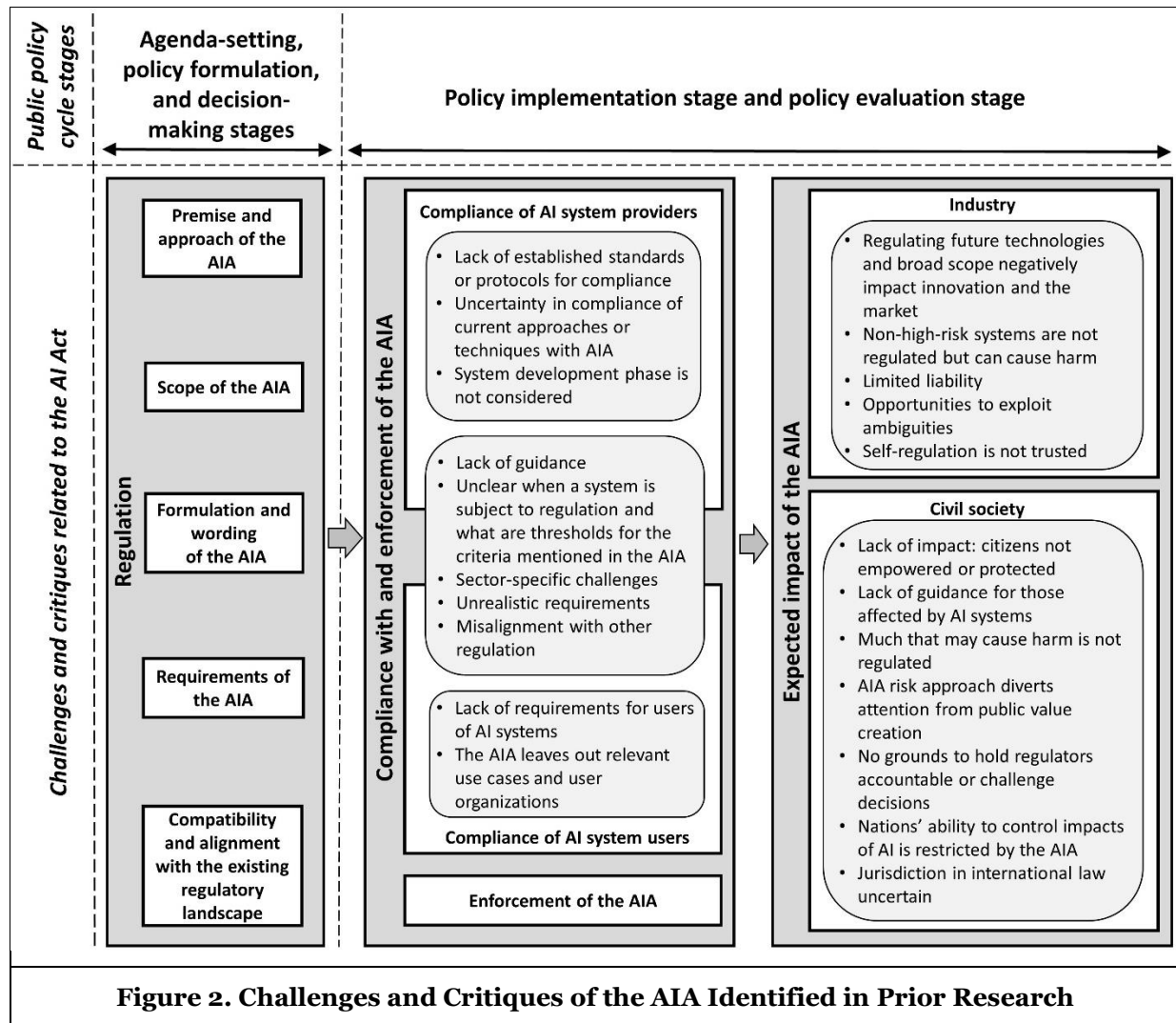
Research theme 1: The role of ambiguity and regulatory intermediaries in the context of compliance with and enforcement of the AIA

Theme 1a: Ambiguity in and compliance with regulation. In the context of legal regulation, "regulatory ambiguity" is defined by Luther (2022, p. 1) as: "the uncertainty or inexactness of policies governing a particular action or industry". Our review pointed – in the context of all three themes into which we categorized our findings – towards ambiguity in the AIA **[Q1.1]** and towards its potential consequences such as legal uncertainty and the potential for different actors to exploit these ambiguities **[Q1.2].** Both for organizations that provide AI systems and those that use AI professionally, ambiguity points to future challenges with compliance with the AIA. **[Q1.3]** IS research to date has been largely silent about the topic of ambiguity (see Väyrynen et al., 2022 for a review of ambiguity-related aspects in IS research).

Ambiguity in the AIA was mostly presented as being problematic, as it makes it difficult for industry actors to know what needs to be done to comply with the regulation and opens the possibility to interpret the AIA in ways that might lead to unintended and negative consequences. While policy ambiguity has been seen – either directly or indirectly – as a problem also in prior IS research, it can also be used intentionally, as a tool that enables policymaking (Väyrynen et al., 2022). Considering that the AIA is a horizontal regulation that applies to all industries, a certain degree of ambiguity seems unavoidable and even necessary to allow for the AIA to be applicable to the wide range of industries and AI systems that it intends to cover. We expect struggles over interpretations of the regulation – in the light of ambiguities - to take place over the coming years, e.g., in the context of how "Artificial Intelligence" is defined in the AIA and whether a specific

system would fall under the AIA or not, and whether or not a specific system would be classified high-risk and thus need to adhere to much stricter requirements than lower-risk AI systems. **[Q1.4]**

Theme 1b: The role of regulatory intermediaries in compliance and enforcement of the AIA.
Our review pointed towards challenges with the enforcement of regulation considering the AIA formulation and requirements, including the important question of how and by whom the AIA will be enforced. Bailey and Barley (2020) called for IS research to extend the scope beyond design and use towards power and institutions. How the regulation of AI will function institutionally is still undecided. We call attention to regulatory intermediaries, i.e., government authorities that "play major and varied roles in regulation" (Abbot et al., 2017, p. 14). They are key agents that stand between the regulators and the targets of the regulation (i.e., those who must comply with the regulation), helping the regulator to formulate, implement and enforce regulatory policies. They play a crucial role in whether and how regulation targets implement and adhere to new regulations. "Hard" regulation (such as the AIA represents) is accompanied by "soft" regulation which is formulated by regulatory intermediaries and which prescribes rules or "standards" that usually are not legally binding (Abbott et al., 2017). More recent developments in the AIA policy process point towards the important role of harmonized standards which should make "what are at times vague essential requirements into concrete technical requirements" (Standard Setting, 2022). IS research has already undertaken some inquiries into technology standardization (Lindgren et al., 2021), and the AIA will over the next years provide a fruitful ground for IS research on technology standardization and its role in compliance with the AIA. **[Q1.5]** While it may provide important considerations for the development of the AIA, we do not yet know how the future structures and standards will be shaped and how they may clarify how the AIA is to be interpreted. **[Q1.6]** For example, the AIA outlined the establishment of regulatory sandboxes as a tool that would allow companies to experiment with and explore new, innovative services, products, or business under the supervision of the regulator. Regulatory sandboxes for AI are a potential topic for future IS research, falling in line and building on very recent IS research on regulatory sandboxes in the context of the financial sector and FinTech (e.g., Kraljev et al., 2021). **[Q1.7]**

Research Theme 2: Formulation of legal regulation

We have identified many challenges and concerns in our review, which are related to or arise from the formulation and wording of the AIA, its scope, its premise and approach, its requirements, and potential conflicts with other regulations. All of these can be seen to be negotiated during the policy formulation stage, which has been mostly ignored in earlier IS research on legal regulation. In this stage, the policymaker defines what the public policy should achieve, and policymakers and other stakeholders at this stage usually negotiate about the content of the policy and its textual formulation, before a decision is made on whether to adopt or reject the policy (Howlett and Giest, 2012). For the AIA, but also for other EU-level regulations, the process of policymaking involves the European Parliament (representing EU citizens), the European Council (representing EU governments), and the European Commission (representing the EU's overall interests).[3] These three institutions all may present their own versions of the regulation, like in the case of the AIA. During this process, there may be public consultation periods where anyone can provide opinions/statements on the proposed regulation **[Q2.1]**, there are negotiations between the representatives of different EU governments, and there are processes involved on a country-level during which, e.g., the specific country's own position or propositions for formulating the Council-version of a draft regulation are negotiated. **[Q2.2]** A promising new area for IS research would be to study the policy formulation stage in the legal regulation of technology. In the context of the AIA, the technology itself is of special interest, as AI (including its areas of use, the techniques and methods employed for implementing AI) are developing at an immense and ever-increasing speed.

In our review, we identified critiques related to the AIA's underlying principles and approach, that have directed its scope, wording, formulation, and requirements. These suggest a need to study the language used in the law **[Q2.3]**. Future IS research on legal regulation may find it interesting to examine the variations in language, wording, and requirements among proposals from different institutions **[Q2.4]**.

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[3] For an overview of EU decision-making processes, see: https://european-union.europa.eu/institutions-law-budget/law/how-eu-policy-decided_en

Theme 1: The role of ambiguity and regulatory intermediaries in the context of compliance with and enforcement of the AIA	Theme 2: Formulation of legal regulation
Q1.1: What type of ambiguities arise from the AIA?	**Q2.1**: What discourses arise in public opinions on the AIA, and how do they impact the AIA?
Q1.2a: How does ambiguity lead to legal uncertainty? Which types of ambiguity or which instances of ambiguity lead to a higher/lower degree of legal uncertainty?	**Q2.2**: How do different countries influence European-level regulation formulation? (EU-level view; country-specific process view)
Q1.2b: How are ambiguities in regulation exploited by different stakeholder groups?	**Q2.3**: What formulations in the regulation are those that AI/technology providers and professional users of AI most struggle with?
Q1.3a: How do organizations that develop/use AI/technology that is regulated by ambiguous regulation deal with these ambiguities?	**Q2.4a**: How have certain (potentially problematic) formulations in the regulation been negotiated during the policy-formulation stage, such as the definition of "artificial intelligence"?
Q1.3b: What compliance related challenges do organizations developing vs those that professionally using AI face?	**Q2.4b**: How do the proposals of the European Commission, European Council, and European Parliament differ, and why?
Q1.4: Considering the necessity of having some degree of ambiguity on the one hand in horizontal regulation and the challenges identified in relation to ambiguity or unclarity of the AIA: How much ambiguity is necessary, how much is enough, and when does ambiguity become harmful to aspects such as AI innovation, equality, or fair and unbiased treatment of citizens?	**Q2.4c**: What kind of ambiguities or unclarities are decreased or increased during the policy-formulation stage?
Q1.5: What is the role of standardization bodies and other regulatory intermediaries in decreasing ambiguity?	**Q2.4d**: What discourses can be identified in the policy-formulation stage, whose voices are loudest? (industry; civil society; …?)
Q1.6a: What kind of regulatory intermediaries will be established, given authority, and when during the AIA cycle?	**Theme 3: Longitudinal research covering several policy cycle stages**
Q1.6b: What is the role of regulatory intermediaries in regulatory compliance (on industry level or organization-level)?	**Q3.1a**: How does new technology impact the policy formulation and decision-making stages in a technology-regulation policy process?
Q1.6c: What is the role of regulatory intermediaries in decreasing ambiguity?	**Q3.1b**: How does/did general-purpose AI such as ChatGPT impact the AIA policy process?
Q1.7a: How will regulatory sandboxes be set up in the context of the AIA?	**Q3.1c**: What themes gain in importance or fade away over a policy cycle for a specific regulation (e.g., AIA, DSA, DMA), and why?
Q1.7b: What challenges are connected to regulatory sandboxes for AI technology?	**Q3.2**: How do organizations prepare for a new technology-related regulation (a) during the policy-formulation stage, (b) during the transition period after adoption but before enforcement of the regulation, and (c) after the regulation is being enforced.
Q1.7c. Are there differences in how different countries will set up regulatory sandboxes, and how do these differences affect, e.g., AI-related innovation activities between these countries?	
Q1.7d: Which sectors have a special need for regulatory sandboxes (e.g., healthcare industry, public-sector organizations, etc.) and why?	

Table 1. Proposed Research Themes and Exemplary Questions for Future IS Research

Research Theme 3: Longitudinal research covering several policy cycle stages

We discovered a need for studies over the full policy cycle in technology-related legal regulation. While this is quite understandable that IS research on legal regulation has had a heavy focus on the implementation stage, where development and use of technology under existing legal regulations happens, it has also been recognized that public policymaking is an important yet marginal, research area for IS (e.g., King and Kraemer, 2019). Our literature review showed how aspects that are formulated and negotiated during earlier policy cycle stages immensely impact the implementation and evaluation stages. Attuning to the temporal dynamics requires proper frameworks, for example, the policy cycle (Howlett and Giest, 2012).

Specific themes that seem important or pose challenges may change over the duration of the policy cycle. It is, for example, remarkable that only one paper in our review concerned foundation models (Wójcik, 2022). Apparently, foundation models were not a mainstream research topic during the reviewed timeframe. However, after the ChatGPT launch in November 2022, foundations models, large language models, and general-purpose AI have taken over much of the regulatory discourse in the EU. For example, Politico reported in March 2023 that "ChatGPT broke the EU plan to regulate AI". Academic research is also catching up on these issues (e.g., Helberger and Diakopoulos, 2023). Thus, new topics may emerge as technology develops at a fast pace. As some new issues emerge in policymaking, others fade away. **[Q3.1]**

In addition, studies that would investigate over a longer timespan whether and how organizations prepare for regulation on the one hand at the time when the regulation is still being in-the-making (policy-formulation and decision-making stages) and on the other hand after a new regulation is being adopted/become effective (implementation stage) might provide valuable insight. In addition to the AIA, also other regulations might be of interest for IS research to address similar questions, such as the Digital Services Act and the Digital Market Act, which entered into force in late 2022. These two Acts seek to, e.g., ensure an open and fair platform environment and decrease large platform provider's power as gatekeepers in digital markets and thus might interest platform researchers. Similarly, the Data Act (policy-formulation stage), which seeks to clarify under which conditions and by whom value may be created from data, may be of interest for IS research on data and data governance. **[Q3.2]**

Conclusion

The European Commission proposed the European Artificial Intelligence Act (AIA) in April 2021. While the Act has garnered significant attention, research has highlighted also various challenges and critiques. In our systematic literature review, we have synthesized the existing research published between 2021 and Autumn 2022 on the AIA to identify these challenges. The AIA holds great significance for IS practice and research, which has already been studying AI-related issues and regulation. Our review highlights various challenges related to the AIA but also suggests directions for future IS research and opportunities to study policy-in-the-making. As is the case for most systematic literature reviews, choices made during the search for literature poses limitations to our review: the chosen timeline (2021 to autumn 2022), including only English-language publications, and limiting our search to five databases and to scientific publications only. As our work was not limited to IS top journals and their discussions around the AIA, it can provide some useful insights into the wider concerns related to this regulation. Another limitation is that we only selected articles that criticized and pointed out challenges in the AIA draft, which may create a perception that the outlook is more negative than it is. Furthermore, we did not evaluate whether the claims made in the literature about challenges and critique regarding the AIA are accurate or not. We chose this approach to facilitate future research on whether these concerns materialize and how the regulation process responds to them. Our literature review, but also our discussion and proposition of research questions for future IS research on legal regulation was focused on European legislation, this poses a limitation. Similar important regulative initiatives in different policy cycle stages are ongoing in other geographic regions as well, and we invite IS researchers to pay attention to these.

Acknowledgements

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(*-mark indicates that the article is part of the systematic literature review)
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