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Towards experimental standardization for AI governance in the EU

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ABSTRACT

The EU has adopted a hybrid governance approach to address the challenges posed by Artificial Intelligence (AI), emphasizing the role of harmonized European standards (HES). Despite advantages in expertise and flexibility, HES processes face legitimacy problems and struggle with epistemic gaps in the context of AI. This article addresses the problems that characterize HES processes by outlining the conceptual need, theoretical basis, and practical application of *experimental standardization*, which is defined as an *ex-ante* evaluation method that can be used to test standards for their effects and effectiveness. Experimental standardization is based on theoretical and practical developments in experimental governance, legislation, and innovation. Aligned with ideas and frameworks like Science for Policy and evidence-based policymaking, it enables co-creation between science and policymaking. We apply the proposed concept in the context of HES processes, where we submit that experimental standardization contributes to increasing throughput and output legitimacy, addressing epistemic gaps, and generating new regulatory knowledge.

1. Introduction

Grand expectations from Artificial Intelligence (AI) are accompanied by significant governance, ethical, legal, and societal implications. These implications manifest in numerous areas. AI affects climate change, law enforcement, medicine, agriculture, social media, the creative and beauty industry, and various other sectors [1–4]. Beyond sector-specific challenges, the technological innovation involving AI, such as algorithmic decision-making, robotics, and big data analysis, entails apparent and hidden dissonances with general norms and frameworks [5,6]. Dissonances may arise due to the novelty of practices and a slow regulatory pace [7], but there are also other factors at play. Outdated policies no longer answer the problems [8], or they may be technology-neutral, so developers need help finding suitable answers to their problems [9]. New practices, like helping wheelchair users walk again, entail novel and unknown challenges, such as neglecting traditional accessibility standards [10]. Additionally, structures that connect empirical findings with policy cycles are less present than in other fields, like the chemical industry [11]. Given the significant challenges posed by AI and the meticulous regulation of other critical areas affecting human life, such as chemistry or aviation, it is crucial to address the regulatory issues surrounding AI usage in society [12].

To respond to these challenges, the EU and governments worldwide are focusing increasingly on AI technology development from legal, ethical, and regulatory perspectives [13]. Exhibiting a pronounced determination to regulate AI, the EU has enacted laws like the Digital Services Act [14] and the Data Governance Act [15]. New laws, such as the AI Act and AI liability rules [14,16,17], are proposed, too. From a public governance perspective, EU law requirements often do not specify how they should be implemented technically, to ensure laws stay relevant with new technical solutions ([18], p. 7; [19]). The design of the proposed AI Act conforms to this technique. Such a 'future-proof' regulatory choice invites the need for the further specification of requirements in other, more flexible mechanisms. The EU addresses this challenge by delegating the task of further specifying the EU law requirements to lower governance levels or to standardization bodies [20].

In this article, we focus on Harmonized European Standards (HES), which is a particular mode through which the EU supplements general legal rules with more concrete specifications [21]. The role of HES for AI governance purposes in the EU is apparent especially in the proposed AI Act [17].[1] HES are developed by a European Standardisation

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[1] For instance, recital 61, article 9 and 12 AI Act.

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Organisation (ESO),[2] after a mandate from the European Commission (EC). From a legal point of view, conforming with a HES is equated with legal compliance of the EU law requirements that the HES implements.

HES processes are an example of hybrid governance, a governance activity that is performed by both public and private actors, often alternatively termed 'co-regulation' [22]. In the EU, policy programmes like better regulation and smart regulation [23,24] rely on hybrid governance methods that combine public and private actors. Theoretically, hybrid governance methods are incorporated into various frameworks, such as collaborative governance [25] and multi-level governance [26].

Hybrid governance is useful for harnessing technical knowledge that may otherwise not be accessible via public governance. However, it raises fundamental legitimacy problems, which manifest mainly in the transparency and accountability of decision-making processes, and the effectiveness of standards in various groups in society [9,27,28]. As a result, hybrid governance presents a technocratic structure and delegates political decision-making to privately collected experts [29–31]. In addition to legitimacy challenges, the governance of AI is hindered by epistemic problems. The technical know-how on AI's impact and effects on society, and how to regulate them, is still in its development phase [32,33]. In other words, the successful governance of AI is not only a matter of standardizing the best practices, but it depends on generating new technical and regulatory knowledge on what the best practices can be. While computer science and engineering scholarship on topics like explainability, transparency, fairness, and security is growing [34] it lacks direct ways to connect with the policy cycle [9].

Theoretical and practical developments relying on experimentation have been advanced as a viable means of connecting science with policymaking. They are embodied in frameworks like *Science for Policy* and evidence-based policymaking. These methods and frameworks have been beneficial to sectors like chemistry, pharmaceutics, or food, leading to a higher quality and safety of products [5]. Recently, these ideas and methods are increasingly explored in the realm of AI and robotics.[3] In the field of regulation and governance, the rationale behind Science for Policy and evidence-based policymaking connects with experimentation methods. For analytical purposes, we distinguish between three applications of experimental methods: *experimental governance, experimental legislation, and experimental innovation*. These experimental methods interact and share similarities with each other. Nevertheless, it proves beneficial to distinguish between them for analytical reasons since they serve different purposes.

Hence, new regulatory knowledge may be derived by experimenting on what is the best governance strategy [35,36], what is the most effective legislative measure for a specific problem [37,38], and what are the (legal, societal, and ethical) effects of innovative products and services [39,40]. However, the potential of experimentation in the context of AI standardization has received little to no attention in the existing literature [41]. The experimental method for AI standardization may prove beneficial for gaining knowledge on technological impacts [42]. Moreover, experimentation may prove useful for mitigative and remedial strategies and increasing legitimacy via the inclusion of different actors [9,43,44].

These theoretical and practical developments facilitate and enable the opportunity to apply experimentation methods in standardization, that is, *experimental standardization* for the AI governance in the EU. Experimental standardization refers to incorporating experimentation as an ex-ante evaluation method that tests standards for their effects and effectiveness, thereby increasing the legitimacy of standardization processes, addressing epistemic gaps, and generating new regulatory knowledge. We apply this concept to the case of HES, considering the relevance of HES for the governance of AI in the EU [17,45]. To that end, this article constructs an understanding of the concept and application of experimental standardization for HES processes, including its role in remedying the legitimacy challenges of HES processes. Our proposal may be helpful in other similar contexts besides AI and HES. For example, it may be relevant for the standards used in web content accessibility [46] . We hope that by providing a contextual application of this concept, in the case of AI and HES, we offer guidance for extending the idea to other contexts.

Section 2 explores the EU hybrid governance processes for developing HES, highlighting relevant criticism and gaps. Section 3 delves into experimentation literature, analyzing experimental governance, legislation, and innovation concepts. Section 4 outlines a proposal for the concept of "experimental standardization," focusing on HES development in the EU context. Section 5 concludes the article and explores areas for further research.

2. The practice of HES as a hybrid governance mode

2.1. Harmonized European standards

EU law defines HES as "a European standard adopted based on a request made by the Commission for the application of Union harmonization legislation" [21]. The role of standards for the application of EU law was formalized in the 'new approach' to EU governance. Through a series of EU laws,[4] which culminated with the 1985 Council Resolution [47], the new approach presented four principles: a. EU laws shall harmonize only "essential safety requirements"; b. these are to be further specified in technical standards by European Standardisation Organisations (ESOs); c. these standards, referred to as HES, are voluntary; and d. complying with the standards breeds a presumption of conformity with EU law [48].

The first step towards developing HES is a set of high-level criteria specified in EU laws (see Fig. 1). These criteria serve a particular overarching normative goal, such as product safety. First, EU law refers to the need to develop technical standards. After that, the EC mandates the relevant ESO, the European Committee for Standardization (CEN) or the European Committee for Electrotechnical Standardization (CENELEC), to develop a standard that applies the EU law requirements. The ESO may accept or reject the mandate. Acceptance forms a contractual relationship between the EC and ESO, giving the EC oversight rights but no control over the contents of the standards. The process is regulated by law [21] and further clarified in the rules of the ESO. In short, a working group or a technical committee created by the ESO prepares a draft standard for public consultation and feedback from interested parties before the Technical Board of the ESO approves it. The working groups and technical committees must include various interested and affected stakeholders during the drafting and consultation. Once consulted and developed, the draft standard is then sent to the Technical Board for approval. Afterward, it is sent to the EC, which checks if the set standard fits the mandate and EU law. If this is the case, the standard is published via a European Commission (EC) implementing the decision in the Official Journal of the European Union (OJEU) as a harmonized standard. After a period of 5 years, standards are subjected to a review that may lead to a confirmation, modification, or withdrawal of the standard.

According to the jurisprudence of the European Court of Justice (ECJ) [49], a HES is part of EU law, and while adoption of the standard is voluntary, conformity with the standard equals compliance with the EU laws that the standard implements [50]. Moreover, besides HES, which

[2] European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC).

[3] *See* the ERC Starting Grant Safe & Sound https://www.universiteitleiden.nl/en/research/research-projects/law/safe–sound-towards-evidence-based-policies-for-safe-and-sound-robots.

[4] For instance, the Information Directive, which defines standards as non-compulsory and adopted by a "recognised standardisation body", while designating CEN and CENELEC as "European Standardisation Bodies".

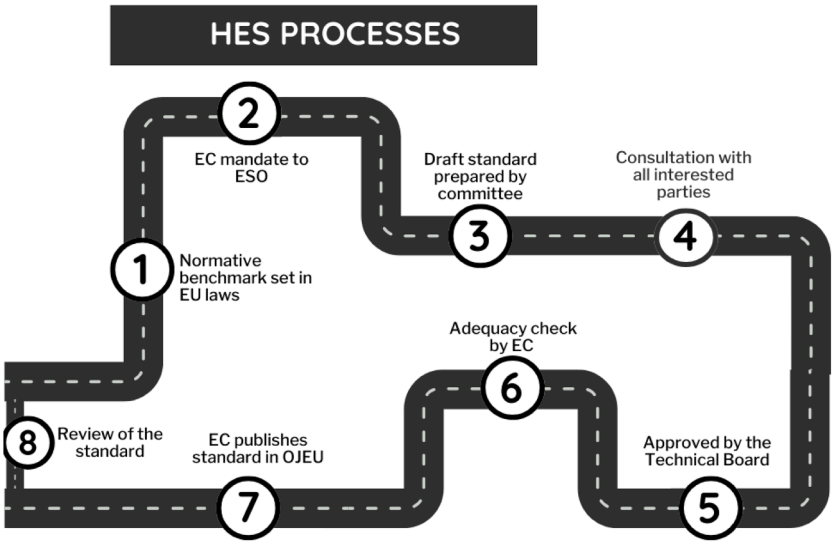

Fig. 1. Harmonized European Standard processes according to EU law.

follow the procedure described above, there are also so-called 'European standards', defined as standards adopted by an ESO [21]. The main difference between HES and European standards is that anyone, not just the EC, may propose a European standard. The ESO follows the same process for the development and approval of the standard, after which the standard must be adopted by all national standardization organizations (NSOs), although the European standard is not necessarily published in the OJEU.

2.2. *The problems with HES processes: legitimacy and epistemic gaps*

HES are a particular form of hybrid governance process in the EU, involving non-state actors in public governance matters. While this mode of governance is promoted as more efficient than public governance methods [18], it faces serious legitimacy problems and struggles with epistemic gaps. These problems precede the use of AI, as some of these considerations have been formulated since the introduction of the 'new approach' in the 1980s [47]. However, in this section, we shall apply and conform these critical remarks and objections to the scope of our paper, which is AI governance.

First, due to its technocratic nature, HES processes shift political decision-making away from public institutions and closer to private expert groups [29–31]. Driven by private expertise, HES processes may undermine the purposes and normative values of public governance [51] without being subject to the rule of law guarantees [45,52]. As a result, political legitimacy questions connect closely to the privately driven and technocratic nature of HES processes.

More precisely, standardization processes are criticized for lack of diversity and inclusion as normative and standardizing criteria [53,54]. Partly due to the path dependence of product safety regulation, standardization of AI has been focused primarily on health and (physical) safety considerations. However, existing scholarship underscores how intersectional considerations (e.g., age, health condition, gender, sex, origin, religion, and others) play a role in, for instance, human-robot interaction and may challenge privacy, safety, and the right against discrimination [43,55]. The unique characteristics concerning women, older adults, and vulnerable users are critical for safety. If disregarded during the design of AI, they cause significant harm to users [56,57]. These considerations are particularly essential with technologies that afford close and intimate user interaction, such as exoskeletons [10]. Although standardization organizations recognize these considerations in principle, they often do not act on them. Consequently, they do not implement them as safeguards in international or European standardization processes [43].

Second, there are epistemic gaps in the technical state of the art needed to regulate the design and use of AI via HES. From a computer science and engineering perspective, many solutions and mitigation strategies, concerning transparency, explainability, fairness, and privacy by design, to name a few, are still in development [34,58]. To illustrate this point, there is insufficient evidence to what extent gender and sex considerations affect the performance of algorithms used in medicine, [59,60], or how intersectional considerations affect robot design, which represents a salient problem for patient safety [61,62]. Even when these concepts are academically explored, they either lack appropriate standardization to help developers implement them (as in the case of the standard on privacy-by-design),[5] or tests and evaluations have not been implemented coherently (as in the case of ISO/TR 23482-1:2020 Implementing ISO 13482:2014 on safety requirements for personal care robots).[6] This situation leaves regulators uncertain over how to effectively govern AI [33]. Consequentially, users of AI, and particularly marginalized and vulnerable groups, bear the heaviest burden for this regulatory uncertainty [63], being exposed to situations where damage occurs and liability mechanisms may fail [64].

To synthesize the criticism outlined so far, HES processes face legitimacy and epistemic problems. First, the technocratic nature of HES processes challenges legitimacy. There is a concerning lack of transparency and inclusion, and no mechanisms are in place to anticipate how HES processes affect particular groups. Second, epistemic problems arise from lack of technical and regulatory knowledge needed to standardize the best practices and foresee their effects on users. Table 1 summarizes the different issues in this context. Legitimacy problems may be categorized into three types, if we adopt a framework from political science [65,66]. Input legitimacy concerns the formation of institutions and actors involved in political and normative decision-making. Output legitimacy concerns the effects and effectiveness of such decisions, whereas throughput legitimacy is concerned with transparency, accountability, and accessibility [66] (See Table 1).

[5] To be precise, ISO 31700-1 on privacy by design (for high-level requirements) in consumer protection is being developed, along with ISO 3700 and ISO/IEC TS 27560.

[6] ISO/TR 23482-1:2020 reads: "At the time of publication, the test methods described in this document have not been implemented or evaluated broadly. Due to a lack of test facilities worldwide able to conduct such tests, it has not been possible to conduct formal round robin tests. Users of this document are therefore advised to apply the tests with care."

Table 1
Challenges and criticism of HES processes for AI.

Challenges and criticism towards HES processes for AI		
Legitimacy		Epistemic
Input	The composition of committees	Regulatory uncertainty and lack of technical knowledge
Throughput	The transparency, oversight, and inclusiveness of the process	
Output	The effectiveness and effects of standards	

Table 2
Envisioned benefits of experimental standardization for HES processes.

Legitimacy		Epistemic
Throughput	Enhanced accountability, increased transparency, more inclusivity, and better oversight.	Generating new technical and regulatory knowledge.
Output	Improving the effectiveness and preventing side effects.	Facilitating a potential decentralization of HES processes.

3. Trial and error: experimentation in governance, legislation, and innovation

The challenges exposed in the previous sections connect with literature that calls for more proactive, dynamic, and responsive regulation and governance [25,67,68]. In the field of the regulation of new technologies, literature advances different forms of experimentation [38,69,70]. They relate to calls for generating policy-relevant data through technological experimentation [5,71]. This section discusses the concepts and methods of experimentation in regulation and governance. For analytical purposes, we distinguish between three types of application of experimental methods: experimental *governance* [35], experimental *legislation* [37,38], and experimental *innovation* [39,40]. These experimental methods serve different purposes. Experimental governance is useful to understand the effectiveness of policies on different governance levels. Experimental legislation serves to understand how effective a legislative measure is in relation to a specific regulatory problem, whereas experimental innovation serves to understand what type of effects and side-effects ought to be expected from the deployment of innovative products and services. We will delve deeper into each of these types of experimentation.

3.1. Experimental governance

Experimental governance refers to governance structures that enable the testing of policies on lower governance levels, creating ways for mutual learning from the results thereof [35,36]. Experimental governance is often traced and connected to ideas and theories like states-as-laboratories [72] and regulatory competition [73,74]. States-as-laboratories denotes that one particular state, should they freely choose to, may serve as a socio-economic laboratory for new policies, as first defined by Justice Brandeis [75]. This idea played a role in the US federal law-making process, incorporating the experiences of individual states in the design of federal rules and standards [72,76].

The economic theory of regulatory competition claims that a decentralized governance structure where jurisdictions are free to compete to attract residents can lead to more efficient policies and increased social welfare [74]. Its rationale posits that competing governance alternatives would enable individuals to choose their preferred governance features [73,77]. Regulatory competition and states-as-laboratories argue that regulatory knowledge may be derived by allowing the testing of various competing options rather than opting for a harmonized solution. As a result, these ideas developed as an alternative and in opposition to centralized governance and harmonization policies.

The ideas of decentralization and competition tend to overlook and disregard contextual settings and have lost ground to more nuanced syntheses between harmonization and decentralization [78]. They neglect pragmatic factors for individual mobility [79] or lead to a 'race to the bottom' with jurisdictions lowering compliance standards to attract businesses [80,81]. In addition, legal jurisdictions may not be ideal settings for experiments and competition because governments do not make their aims explicit enough to evaluate the legislative measure properly [72].

From an EU governance perspective, the synthesis between harmonization and decentralization is embodied in the subsidiarity principle (Art. 5 (3) Treaty of Lisbon) [79,82], which guarantees some governance rights for national and local governing bodies. Through the subsidiarity principle, lower governance levels are allowed a certain level of autonomy in designing ways to implement policy goals that are harmonized on the EU level. Being afforded this level of autonomy, local governance levels must report on their performance and participate in what may be called 'governance peer review', where their local results

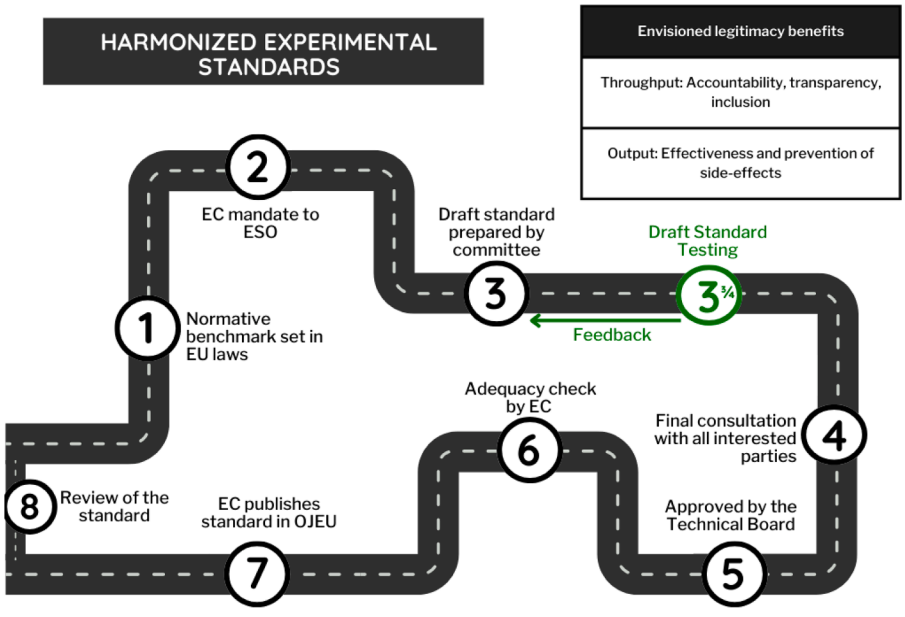

Fig. 2. Proposed HES processes with experimental standardisation as an evaluation method.

are compared with results from other local governments ([35], p. 274). This interaction between various levels introduces a form of experimentation and, to an extent, competition between governance levels. They are free to design and implement rules but are constrained by the evaluation of how well their policies fared compared to other governments. This form of governance, often referred as multi-level governance, is characteristic of the EU and enables lower governance levels to influence policymaking at higher levels without any structural and formal rights of so doing [26,36]. However, the multi-level governance structures in the EU do not materialize in HES processes, which are harmonized and centralized in the works of ESOs. Although ESOs comprise national standardization bodies (NSBs), the latter do not have the structural rights to experiment with standards but can only voice their opinion and participate during the development of HES.

3.2. Experimental legislation

Experimental legislation is "legislation enacted for a limited period to examine if a particular legislative measure will effectively achieve certain goals" [83]. In situations of uncertainty, experimental legislation may help to develop regulatory knowledge by testing if specific legal interventions may prove effective for the regulatory problem at hand.

Experimental legislation differs from experimental governance in that it focuses on testing specific legislations for their effectiveness rather than designing governance structures that enable experimentation. It differs also from experimental innovation, which involves evaluating the effects of innovative products/services [84]. Moreover, experimental legislation differs from sunset laws or sunset clauses [85] insofar as the latter are designed to end, although they may be extended. In contrast, experimental legislation is designed to be enacted indefinitely if it proves successful during its temporary testing.

Scholars have identified four elements of experimental legislation that differentiate it from other related concepts ([70], p. 542):

A. It is temporary;
B. It has a fixed scope, place, addressees, and time;
C. It shall be subject to evaluation; and
D. If successful, it may be expanded and applied to other contexts.

Experimental legislation was internalized in policymaking programmes such as 'better regulation' [23] and "smart regulation" [24]. Pursuing the aim of evidence-based decision-making, these policymaking programs aim at incorporating empirical evidence to produce more effective policies [31]. Impact assessments are one of the main instruments, encompassing all three legislative bodies in the EU [86], along with various ex-ante evaluations often involving cost-benefit analyses [87]. Ex-post evaluation methods are often promoted as more scientific insofar as the testing of policies produces hard evidence, whereas ex-ante evaluation methods rely on assessment, feedback, and discourse ([70], p. 540). From an EU governance perspective, experimental legislation is viewed as an ex-post method of evaluation. It is possible only after the law has been enacted. However, it bears a solid retrospective feature, since the law is enacted for a temporary time and may be easily ended [70].

An early example of the application of experimental legislation in the EU is in the field of taxes [88]. To test if reduced VAT rates would create more jobs in specific sectors, Member States could apply for authorization to lower VAT rates for up to three years. Interestingly, although the results of the experiment showed no impact of lower VAT rates on employment, as tax reduction was merely used to increase profit margins [89], the policy was extended past its original timeline, proving a case of regulatory disconnect between empirical evidence and policymaking [70,90]. As experimental legislation has been applied since the 1970s in France [38], more examples have followed. The Netherlands has issued experimental legislation for civil judicial procedures [91], whereas Finland has launched a program experimenting with basic income [92].

Experimental legislation raises constitutional concerns. From an EU perspective, they are addressed on the judicial and legislative levels, as well as from legal scholarship. The French constitution recognizes that experimental laws may be adopted at national and local levels to test the effect of new legislative measures (French Constitution, 1958, Art. 37 and 72). On the EU constitutional level, experimental legislation is not explicitly mentioned at the EU constitutional level. However, in a Court of Justice of the European Union (CJEU) case [93], Advocate General Maduro has tackled the issue of how experimental legislation may challenge the EU principle of equal treatment of market players, considering that one of the characteristics of experimental legislation is that it applies to a defined number of participants and not all market actors [94]. According to the Advocate General, experimental legislation does not challenge equal treatment when it has a temporary character, and the entry criteria are objective. Along the same lines, legal scholarship argues that experimental legislation must adequately justify its design choices and not generate situations of unacceptable inequality to abide by the principles of legal certainty, equal treatment, transparency, and proportionality [38,84,95].

3.3. Experimental innovation and regulatory sandboxes

Experimental innovation is another form of experimentation, relates to testing innovative products and services. It is referred to alternatively as legislation for experimentation [39]. This type of experimentation is used primarily in contexts when it is unclear what the effects of a new product or service will be; for instance, offering financial advice through AI (i.e., Robo-advice) [40]. Experimenting with innovative and potentially disruptive products/services may help to gain regulatory knowledge of their effects before deciding how to regulate them [36]. On the one hand, experimentation with products and services requires laws that set the criteria and allow the experimentation of new products/services [39,40]. These laws specify the scope of experimentation, the type of products/services to experiment with, and the type of actors involved [38,70]. On the other hand, this form of experimentation requires practical affordances, such as a safe and controlled testing environment, which regulatory sandboxes meet.

Regulatory sandboxes enable testing products and services within a controlled risks and supervision framework, informing regulatory policy [96–98]. The testing and experimentation of innovative products/services should be conducted in an environment that is a compromise between a laboratory (safe but too abstract) and the real world (real but too risky) [39]. In the realm of robotics and self-driving cars, this has taken the shape of testing zones,[7] although it is only recently that these environments have been proposed as potential policy-relevant data generator tools [43,57,71].

Most regulatory sandboxes in the EU are sector-specific and were developed in response to FinTech innovation [40]. On the AI and robotics front, the Norwegian Data Protection Authority set up a regulatory sandbox on responsible AI in 2020.[8] The Commission Nationale Informatique & Libertés (CNIL) Sandbox Initiative for Health Data aims to develop privacy-by-design solutions for healthcare [99]. The role of regulatory sandboxes is visible in the AI Act, Article 53 of which refers to AI regulatory sandboxes as a measure in support of innovation and defines them as a "controlled environment that facilitates the development, testing, and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan" [17].

These advancements are the nascent stages of a broader spectrum of

[7] *See* the facilities created for example by the European project Eurobench: https://eurobench2020.eu/.

[8] *See* for instance: https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/.

progress. The AI Testing and Experimentation Facilities (TEFs) introduced by the European Commission under the Digital Europe program are developed to test and experiment on state-of-the-art AI and robotic applications. A practical example may help illustrate the point. The European Union's H2020-funded EUROBENCH set the first framework for developing benchmarks for robotic systems, particularly physical assistant robots (e.g., exoskeletons) and humanoid robots [100]. The project aimed to devise methods and mechanisms to evaluate robotic devices in a rigorous and replicable way. In this vein, the H2020 EUROBENCH project created two testing facilities, one for humanoid robots and one for wearable robots, that include devices necessary to test bipedal systems under a multifaceted perspective. The EUROBENCH project welcomed the FSTP PROPELLING, which stood for 'Pushing robot development for law-making' and explored how robot testing facilities could generate policy-relevant knowledge for robot technologies [43]. The results and findings from testing suggest that standards should take a more holistic, user-centered approach toward robot safety already in its design phase, understanding how gender, age, sex, and disability interconnect in (e.g., physical assistant) robots and affect user safety [42].

Regulatory sandboxes and TEFs are comprised of a similar structure. After designing the environment and defining its scope, the governing authority establishes the eligibility criteria for entry into the sandbox. These criteria may specify the sector or the type of businesses that can apply for entry [40]. Moreover, regulatory sandboxes must outline the protection and safeguards for consumers involved in the sandbox. For instance, the AI Act specifies that participants in any AI sandbox must be compensated for any harm borne, according to EU and Member State (MS) liability rules (Art. 53). Governing authorities must specify the sandboxing timeframe and which rules, if any, must be relaxed during this timeframe. MSs are not always allowed to derogate EU laws, even in brief sandbox cases, so this process stage requires careful calibration with EU law [40].

On a practical level, some examples of how regulatory sandboxes can facilitate the development of regulatory and governance knowledge for AI and robotics are:

1. **AI algorithm testing**: In a regulatory sandbox, companies can test their AI systems in a controlled environment to identify potential risks and biases. This can help regulators develop guidelines for developing and deploying AI algorithms, such as requirements for transparency and accountability.
2. **Robotic systems validation**: Regulatory sandboxes can validate robotic systems and identify potential safety hazards. This validation can help regulators develop safety standards for robotic systems, such as requirements for emergency shutdown and fail-safe mechanisms. An example would be the methodological framework developed by the H2020 Eurobench project, where start-ups are invited to apply benchmarking procedures to a wide range of robotic platforms and laboratory conditions to efficiently test robotic platforms at any stage of development, from early prototyping to commercial products.[9]
3. **Collaboration between regulators and industry:** Regulatory sandboxes can provide a platform for cooperation between regulators and industry, allowing regulators to work closely with companies for regulatory and governance purposes. This cooperation may help ensure that rules are based on a solid understanding of the technology and its potential risks and benefits. An example is the Tokku Zones in Japan, environments that allow preferential regulatory measures for academic institutions and private companies to test their robots, for instance, on public roads [71]. In the UK, the Robotics and Artificial Intelligence Industry Lab (RAIL)[10] is a regulatory sandbox that provides a testing ground for robotics and AI companies. RAIL aims to promote innovation while ensuring public safety, and it works with regulators to develop effective regulations for these technologies. Companies can test their technologies in a controlled environment and receive feedback from regulators, helping to ensure that their products comply with regulatory requirements.
4. **New business models testing:** Regulatory sandboxes can be used to test new business models incorporating AI and robotics, such as autonomous delivery systems or automated customer service. This possibility can help regulators develop rules that promote innovation while protecting consumer rights and ensuring public safety.

4. Experimental standardisation and its application in harmonized European standardisation processes

Taking stock of theoretical and practical developments in experimental governance, legislation, and innovation, we advance a fourth type, *experimental standardization,* which is be defined as an *ex-ante* evaluation method that consists of testing standards for their effects and effectiveness. This article submits that experimental standardization assumes a functional role that supports and improves HES processes, which struggle with legitimacy challenges and epistemic gaps. The proposed concept of experimental standardization plays a contributing role in remedying parts of the identified problems. Specifically, introducing experimental methods contributes to the throughput and output legitimacy of HES processes. Throughput legitimacy is improved by creating the possibility for enhanced transparency, enabling a more inclusive process, and offering better oversight and presence of potentially affected stakeholders. Output legitimacy is supported by the ability of experimental standardization to address epistemic gaps by generating new technical and regulatory knowledge. This section outlines the basis for this concept and its application in HES processes. We construct the concept of experimental standardisation based on four elements: purpose, method, environment, and actors.

The *purpose* of experimental standardization is to test both the effectiveness and effects of standardization. Their effectiveness is relative to the normative benchmark set in EU laws and the mandate given by the EC. For instance, article 13 of the proposed AI Act requires a certain level of transparency and explainability from AI applications. Therefore, a HES on transparency of AI must implement the AI Act's normative requirements in technical standards. The proposed HES would be tested against this normative benchmark to check if users can internalize and operationalize the information provided by the AI application. As a result, the test against the normative benchmark evaluates the effectiveness and adequacy of standards. Standards may also be tested concerning their effects, which is different from their effectiveness. A standard may be effective regarding its intended purpose, but it may nonetheless have unintended effects [58]. The testing of standards relative to their potential effects is particularly significant for vulnerable groups, who are majorly affected by the unintended effects of design [43,56].

In terms of *methods*, from an EU law perspective, experimental standardization can be understood as an evaluation method. Evaluation methods are used in enacting laws in the EU, either on an *ex-ante* or *ex-post* basis. *Ex-ante* methods include risk assessments, cost-benefit analyses, and consultation with interested and affected groups [86]. The purpose is to gather information and assess the impact of new laws before they are enacted. *Ex-post* methods, including monitoring and performance evaluations, are used after a law has been approved. Experimental legislation, for instance, is considered an ex-post evaluation method since laws must be approved before they are experimented on [70]. Experimental standardization may function as an *ex-ante* evaluation method. After a HES is proposed and before it is approved, the standard may be experimentally tested to gain knowledge of the effects and effectiveness of the standard. In this regard, experimental

[9] See https://eurobench2020.eu/abstract/objectives/.
[10] See https://www.raillab.org/.

standardization differs from experimental legislation in that the latter is an *ex-post* evaluation method, and the former is an *ex-ante* evaluation method. The difference is owed to the more complex nature of the legislation, compared to standardization. The open-ended and broad nature of legislation complicates the possibility of testing new laws in regulatory sandboxes and similar testing facilities, requiring the actual approval of legislation for experimentation purposes. On the other hand, standards possess a more technical and practical nature, enabling their testing in safe and controlled environments before approval.

Such experimental testing exercises may occur in *environments* where the testing of innovative products and services occurs. Therefore, regulatory sandboxes and TEFs would be adequate locations because they comprise the practical affordances needed to test the innovative products and services that will be subject to standardization. From a legal and practical point of view, policymakers must outline the criteria and rules that ensure the protection and safeguards of the consumers participating in the testing. It is also necessary to specify which rules must be relaxed during testing [40,71], and which mechanisms shall be used to evaluate the effectiveness of these relaxations. The addition of experimental standardization in regulatory sandboxes and TEFs would lead to higher costs for the maintenance of these facilities and the administration of testing processes. Currently, these facilities are supported by public financing. For instance, TEFs are supported by the EC, through the Digital Europe Programme, and the Member States.[11] Therefore, experimental standardization, having a public benefit, may continue to be supported by public financing. However, it is also possible for private actors to support such initiatives, which occurred partially with TEFs.

The introduction of experimental standardization as an evaluation method facilitates the role and inclusion of various *actors,* offering the opportunity for enhanced accountability. HES processes would benefit from increased transparency, more inclusivity, and better oversight. From a public governance perspective, representatives of public bodies, like the EC, are afforded an additional opportunity to oversee the development of HES on an *ex-ante* basis. The oversight role of public bodies is relevant for both the effectiveness (ensuring the standard adequately implements the mandate issued by the EC) and the effects of HES (preventing unwanted side effects). At the same time, experimental testing of proposed standards enables the inclusion of stakeholders from both the public and private spheres with a legitimate interest in the process. This would include other public governance bodies, NGOs, civil society, and interest groups [9,43,56]. The results of the experiments must be transparent and accessible to the various actors involved. Interested and potentially affected stakeholders already have access to the development processes of HES, as laid down in the Regulation on European Standardisation [21]. However, being included in the testing of standards offers a higher level of transparency and inclusion, considering that it is often difficult to understand the real effects of standards in their drafting stage. This issue is exacerbated by the fact that public bodies and civil society interest groups may not have the level of expertise that industry actors possess. The unknown side-effects of standards are a challenge already pointed out by standardization bodies, which confirm that the testing of standards is needed to grasp their effects fully.[12]

In addition, experimental standardization as an evaluation method allows the simultaneous testing of competing standards. In its current processes, a single HES is developed through a dialectic negotiation process and compromise between experts collected by the ESO. Introducing experimental testing enables a shift in the logic of developing standards. That means disagreements may be resolved by testing rather than by discussion when there are doubts or conflicts in the development phase. As a result, instead of relying on technocratic dialectics, the process may adopt the scientific logic of trial and error [5]. In addition, the experimental testing of standards enables a potential decentralization of HES processes, allowing new standards to be developed, followed by a mandate of the EC, not only by an organization like the ESO but by any interested public or private organization, including NSBs. Such a change would decentralize HES processes, and various proposed standards would be tested for their objective capacities to implement a normative benchmark (effectiveness) and to understand the impact on the individuals and groups (effects).

As Table 2 indicates, this constructed understanding of experimental standardization would address the legitimacy challenges and epistemic gaps currently in HES processes (see Table 2). Benefits in enhanced accountability, increased transparency, more inclusivity, and better oversight can improve the throughput legitimacy of HES processes. By improving the effectiveness and preventing side effects of HES, experimental standardization contributes to increased output legitimacy.

There are benefits to experimental standardization also concerning the epistemic gaps. The testing of standards through a trial-and-error approach would bring about new technical and regulatory knowledge, which through reiterative feedback loops, would be relevant not only for the finetuning of standards but may have a spill-over effect in society. Furthermore, in the case of AI, epistemic innovation may be encouraged by decentralizing the development of HES. Public and private actors would be incentivized to innovate with technical standards if they were offered an opportunity to have their standards tested and potentially harmonized.

Fig. 2 synthesises the envisioned benefits of experimental standardization and visualises where in HES processes the testing of standards should take place.

Experimental standardization is connected to but different from its experimentalist counterparts. It may seem like experimental governance, considering that standards are a level of governance. This view would be understandable but inaccurate. An important feature of experimental governance is testing policies in different governance levels to gain regulatory knowledge that sifts through the other governance levels. Experimental standardization lacks this multi-level feature and is only concerned with one level of governance: standardization. In this regard, experimental standardization is as different from experimental governance as experimental legislation is, since both standardization and legislation comprise a governance level. If we adopt a multi-level approach through experimental governance, we may test if a regulatory intervention would be more effective on the legislative or standardization level. However, this experiment on governance levels is neither experimental legislation nor experimental standardization; it is experimental governance.

Similarities may be drawn in relation to experimental legislation, too. Both methods are meant to test the effectiveness and effects of a regulatory measure, which is what unites them. Many aspects distinguish them. Standards bear a different nature than laws. They are not mandatory and are produced by non-state actors, in cooperation with state institutions. These differences in nature bear implications for their treatment. For instance, as mentioned earlier, experimental legislation is an *ex-post* evaluation method, whereas experimental standardisation is an ex-ante evaluation method.

Experimental innovation is an *ex-ante* evaluation method, too. Both methods would share a similar environment, i.e., regulatory sandboxes and TEFs. Moreover, standard testing would be performed on an innovative product like AI. However, these methods differ based on their purpose. The evaluation performed through experimental standardisation will focus on the effects of the standard when applied to that product, not on the effects of the product generally. As a result, its focus is narrower as it is not necessarily concerned with the functioning of the AI product, but only with product's aspects that are being standardized based on the tested draft standard. Importantly, these methods differ in

[11] *See* the link for more information: https://digital-strategy.ec.europa.eu/en/activities/testing-and-experimentation-facilities

[12] ISO/TR 23482-1:2020 Robotics—Application of ISO 13482—Part 1: Safety-related test methods.

terms of processes and actors involved. Experimental standardization is conceptualised as an inherent part of the HES processes according to Regulation on European Standardisation [21].

Experimental standardization has flaws and faces challenges. We identify at least four problems that require close attention in the implementation of this concept:

1) First, tests and experiments often go wrong and lead to inaccurate results. Relying on such results may lead to lower effectiveness standards than those that were not subject to testing. Thus, the testing and experimentation must be carefully designed and executed to avoid this risk.
2) Second, private actors that join the experimentation processes, either as part of the standardization committees or as interested stakeholders, still possess superior technical knowledge compared to other stakeholders, such as users. This advantage in technical knowledge may be used to steer the testing and experimentation processes in a way that benefits the industry more than the users. The legitimacy issues, therefore, are only partially resolved merely by the introduction of experimentation.
3) Third, for the results of testing and experimentation to be equally relevant and effective, it is essential that the inclusion of diverse groups, particularly vulnerable ones, is not merely a formal right but a substantive obligation [42].[13] The difference is crucial. For example, although representatives of certain groups may have the right to be included, they may be excluded in effect because they cannot afford to participate due to travel and accommodation costs.
4) Last, the implementation of experimental standardization may decelerate the approval of a HES. Experimentation is an extra step in the process, which may require a few reiterative feedback loops between the drafting stage (step 3) and the testing of the standards (step 3 ¾). The speed with which a HES is approved is considered a strength compared to a legislative process. Experimental standardization thus introduces a trade-off between speed, which may be reduced, and effectiveness, which may be increased.

5. Conclusions and further research

The governance of AI poses a regulatory challenge that the EU is addressing through hybrid governance methods. These methods consist of general normative requirements that are set in EU laws and further specified in technical standards. HES processes embody this logic and are essential to recent legislative actions to regulate AI in the EU, such as the AI Act. However, HES processes struggle with legitimacy problems and epistemic gaps. HES processes face legitimacy issues due to their private technocratic nature, lack of transparency, inclusivity, and oversight, as well as by producing harmful effects on society and particularly vulnerable groups. At the same time, epistemic gaps consist of problems in knowing the effects of new technologies, as well as technical and regulatory uncertainty about the solutions needed to prevent or remedy these effects. Experimental standardization is advanced as a partial remedy to the challenges of HES processes. Experimental standardization derives from theoretical and practical developments in experimental governance, legislation, and innovation. It is an *ex-ante* evaluation method consisting of testing standards for their effects and effectiveness. Proper implementation of experimental methods in this context is vital to accrue the benefits of experimental standardization. In this paper, we have addressed the main practical implications, such as the environment where experimental standardization will occur, the financing of these processes, and the actors who should be involved. However, the proposed concept requires further, more granular work. Three aspects that require further attention from both a research and policymaking perspective are worth highlighting.

First, the crux of experimental standardization is testing. As a result, the effectiveness of testing processes is pivotal to accruing the benefits of experimental standardization. In this regard, further research is required to design and implement the testing processes and practices needed to operationalize the concept of experimental standardization. This, in itself, requires trial and error in understanding what the best practices are. For instance, regulatory sandboxes and TEFs in the EU are primarily designed for testing products and services, that is, experimental innovation. A refinement of these testing locations would be necessary to fit with the requirements for the testing of HES drafts.

Second, the implementation of experimental standardization requires further research in EU law. The processes and practices of testing must be accounted for by EU law. Legitimacy questions that arise require further focus. The oversight of the testing processes, along with the inclusion of various stakeholder and their rights throughout the process, is a matter for EU law. As a result, changes in the Regulation on European Standardisation (2012) would be necessary. Specifically, EU law must specify the conditions within which the testing is conducted, the participants, the evaluation process, cooperation between involved stakeholders, feedback loops, and other aspects that impact effectiveness.

A third area for further research connects with the possibility and potential benefits of a more decentralized architecture for HES processes, a possibility enabled by experimentation methods. In its current form, HES are proposed exclusively by an ESO. In principle, it may be beneficial to allow various public and private actors to propose and test standards that implement a particular normative benchmark set in EU laws and followed by a mandate from the EC. By introducing a form of competition in HES processes, competing standards may be tested against each other for their effectiveness and effects, whereafter, the one that produces better results is harmonized as HES. This possibility, although promising from a theoretical point of view, requires further research from both a legal and economics point of view. Further research must address open questions about the incentives and motivations of other actors to propose standards and the fitness and accuracy of testing procedures to produce results that are sufficiently objective and inarguably distinguish the best standard between proposed ones. Additionally, research and focus on the legitimacy of the processes of a decentralized architecture for HES is necessary. Standardization bodies will maintain their private, industry-oriented nature. Although decentralization of the HES architecture may capitalize on such nature, its inherent legitimacy threats, as underscored in this article, will persist and may pose significant challenges to the effects and effectiveness of HES.

Declaration of competing interest

The authors declare that they have no conflict of interest.

Data availability

No data was used for the research described in the article.

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[13] This aspect was deemed important in the recent EU Product Safety Prize in which some researchers got the price for striving for more inclusion not only in technology development and experimentation, but also in standardization. For more information, *see* p. 16 of https://webgate.ec.europa.eu/safety/consumers/consumers_safety_gate/safetyAward/documents/winners/2023%20%E2%80%93%20Product%20Safety%20Award%20-%20brochure_FINAL.pdf

expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Research Council. Neither the European Union nor the granting authority can be held responsible for them.

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