An iterative regulatory process for robot governance

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Abstract

There is an increasing gap between the policy cycle's speed and that of technological and social change. This gap is becoming broader and more prominent in robotics, i.e., movable machines that perform tasks either automatically or with a degree of autonomy, since current legislation was unprepared for machine learning and autonomous agents and, as a result, often lags behind and does not adequately frame robot technologies. This state of affairs inevitably increases legal uncertainty. It is unclear what regulatory frameworks developers have to follow to comply, often resulting in technology that does not perform well in the wild, is unsafe, and can exacerbate biases and discrimination. This paper explores these issues and considers the background, key findings, and lessons learned of the LIAISON project, which stands for *Liaising robot development and policymaking*, and aims to ideate an alignment model between robots' legal appraisal channeling robot policy development from a hybrid top-down/bottom-up perspective to solve this mismatch. As such, LIAISON seeks to uncover to what extent compliance tools could be used as data generators for robot policy purposes to unravel an optimal regulatory framing for existing and emerging robot technologies.

***Keywords* –** Robot governance, Policy Cycle; Evidence-based policy; Iterative regulatory process, Robot technology.

1 Introduction

New technologies offer possibilities until recently unimaginable and can solve problems faster, better, and more efficiently than ever before, inevitably disrupting our perception of reality (European Parliament, 2020) and leading us to question and challenge existing norms and call for an adequate regulatory response (Fosch-Villaronga and Heldeweg, 2018). Yet, while the development of new technologies rapidly accelerates, an understanding of technology's implications and consequent assessment and legal responsiveness do not always follow suit (Marchant, 2011; Newlands et al., 2021; Holder et al., 2016), creating an increasing gap between the policy cycle's speed and technological and social change (Sucha and Sienkiewicz, 2020). This gap is becoming broader and more prominent in robotics and AI, and in particular in the field of healthcare robots (Fosch-Villaronga, 2019).

The absence of specific regulations on robots, which differ mainly in embodiment and context of use, in which clear procedures, boundaries, and requirements are set to pose an immense challenge for how robot developers integrate legal considerations into their design to make robots safe (Holder et al., 2016; Fosch-Villaronga, 2019). Moreover, the mosaic of existing frameworks focus on physical safety mainly, while robots interact with humans in various ways, including socially, raising other questions than mere physical safety (Martinetti et al., 2021). As a result, current developments fail to provide an adequate level of safety and do not perform well in the wild (Gruber, 2019). In this state of affairs, there is an urge to establish a coordinated regulatory front matching interests that can easily translate into concrete, practical and widely adopted actions for making robots safe to use (Fosch-Villaronga and Heldeweg, 2018).

Some European projects try to address this mismatch by creating different compliance tools, i.e., online tools that help comply with the legislation such as the COVR toolkit.[1] The COVR toolkit was developed by the H2020 COVR project, which stands for 'Being safe around collaborative and versatile robots in shared spaces.' This H2020 project compiles safety regulations for collaborative robots or *cobots*, i.e., robots developed to work in close proximity with humans (Surdilovic et al., 2011) in manufacturing, agriculture, and healthcare. The idea of the project is to present detailed safety assessment instructions to *coboteers* and make the safety assessment process clearer and simpler, which allows, in turn, cobots to be used in a more trustworthy and responsible way.

While these compliance tools may be of help to robot developers in their efforts towards robot legal compliance, new applications may nevertheless fail to fit into existing (robot) categories. Moreover, regulatory frameworks resulting from both private and public policymaking activities (Winfield, 2019) might be outdated, contain confusing categories, or directly be technology-neutral which may be hard to follow for developers who are concerned about their particular development (Fosch-Villaronga, 2019). In this sense, compliance tools are often unidirectional and top-down. They circumscribe the regulatory framework based on abstract categories which leads to them missing the input of robot developers, who might find mismatches and dissonances relevant to policymakers.

Bearing this in mind, the LIAISON Project, a subproject from the H2020 COVR project, investigates to what extent compliance tools, such as the COVR Toolkit, could serve as data generators for emerging robot governance purposes. To test its model, LIAISON focuses on personal care robots (ISO 13482:2014), rehabilitation robots (IEC 80601–2–78–2019), and agricultural robots (ISO 18497:2018).

This contribution explains the inner workings and findings of the LIAISON project. After a short introduction, Section 2 frames the inefficiency and inadequacy of emerging robot governance. Section 3 introduces the LIAISON model and methodology, thereby highlighting the theoretical model envisioned and its practical application. Section 4 highlights the essential findings and lessons learned from building a dynamic framework for evidence-based robot governance as derived throughout the LIAISON project. The paper concludes with a summary of the achieved results and their potential impact on the governance of emerging technologies.

2 Framing the inefficiency and inadequacy of emerging robot governance

Although technology and regulation evolve, they do not always do so simultaneously or in the same direction. Legislation often follows societal changes in framing the rules of power and behavior by establishing rights and obligations for the subjects within society. On the other hand, technological developments are a consequence of scientific outbreaks and pressing needs. A recurrent question is how the law keeps up with such technological advances. The realm of robotics is not an exception, with many developments still largely unregulated. For instance, European Harmonized Standards do not cover automated vehicles, additive manufacturing, collaborative robots/systems, or robots outside the industrial environment (Spiliopoulou-Kaparia, 2017).

Notwithstanding, premature and obtrusive regulation might cripple scientific advancement and prevent potential advantages from materializing (Brundage and Bryson, 2016). This problem might result from ill-informed interventions, where policymakers rush to develop regulatory pieces without sufficient data on the targeted development (Leenes et al., 2017). The lack of a predictable environment and uncertainty regarding the impacts may disincentivize the development and introduction of emergent technologies. However, the ever-present conviction that technological fixes contribute to societal progress usually prevails in the techno-political discourse (Johnston, 2018).

Even in those areas falling within existing regulations, the law often fails to properly guide its addressees' behavior. Robots are complex devices, often combining hardware products, like actuators, with software applications and

[1] *See* https://www.safearoundrobots.com/home.

digital services. Consequently, technology-neutral regulation might fail to squarely frame their development, not to mention the interplay between different instruments and the lack of safeguards for emerging risks. For instance, the impact assessment on the Machinery Directive 2006/42/EC revision highlighted how developers must take several pieces of legislation for the same product to ensure its compatibility with all the applicable norms. Given this room for overlap - the Assessment noted - "there is a risk of applying the wrong piece of legislation and the related voluntary standards, thus negatively influencing safety and compliance of the product." (European Commission, Impact assessment study on the revision of Directive 2006/42/EC on machinery). This remark explains why legal requirements often play a marginal role in robotics. Instead, it is the self-perception of safety risks and economic concerns that often guide developers, who feel pressured to rely on insufficient testing. (see Van Rompaey et al., 2021). Under this uncertainty, neither the regulators nor the addressees know what needs to be done (Sabel et al. 2017), while the users' rights might nevertheless be at stake.

Overlooked in the latest review of "the grand challenges of science robotics" (Yang et al., 2018), this mismatch in technology governance repeatedly appears, calling for issue managers in the form of *Governance Coordinating Committees* (Marchant and Wallach, 2015), Agencies for Robotics and AI (European Parliament, 2017), or emerging technology policy labs (Schatz, 2018). While these bodies could oversee robot and AI developments, what lacks in robot governance is a more thorough understanding of how policies can frame robotics and AI to avoid potential mismatches with the state of the art, enhance innovation, and protect user rights (Fosch-Villaronga and Heldeweg, 2018).

3 LIAISON: Liaising robot development and policymaking

Traditionally, juridical analysis follows top-down approaches to address legal and ethical aspects for robot technologies (Leroux, 2012; Leenes et al., 2017). However, these approaches often presume that the existing laws and norms suffice to understand the consequences of technology. Moreover, there are initiatives that promote reflection upon the consequences of the outcomes of technological research and development (R&D), fostering the incorporation of such reflections into the research or the design process. However, field knowledge could prove useful in identifying gaps and inconsistencies in frameworks governing relevant technologies (Fosch-Villaronga and Golia, 2018).

Following the ideal that lawmaking 'needs to become more proactive, dynamic, and responsive' (Fenwick, Kaal and Vermeulen, 2016), LIAISON proposes the formalization of a communication process between robot developers and regulators from which policies could learn, as depicted in figure 1, thereby channeling robot policy development from a bottom-up perspective towards a hybrid top-down/bottom-up approach.

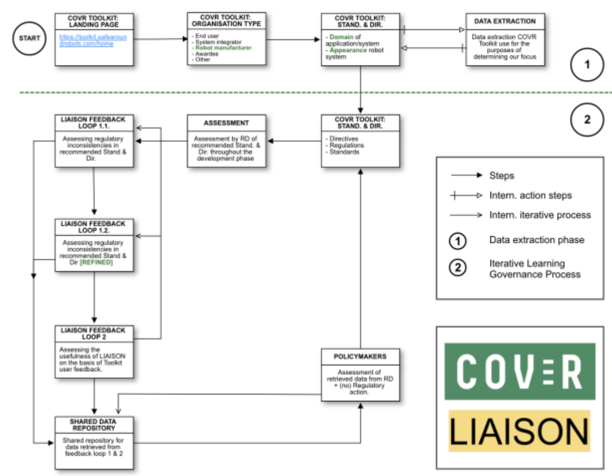


Figure 1. LIAISON model for an iterative regulatory process for robot governance.

By doing so, LIAISON envisions an iterative regulatory process for robot governance, a theoretical model representing a practical step forward in coordinating and aligning robot and regulatory development. It conceives an effective way to extract compliance and technical knowledge from the COVR Toolkit and direct this data to policy and standard makers to unravel an optimal regulatory framing, including decisions to change, revise, or reinterpret existing regulatory frameworks for existing and emerging robot technologies. More practically, the LIAISON project's objective is to clarify what regulatory actions policy and standard makers should take to provide compliance guidance, explain unclear concepts or uncertain applicability domains to improve legal certainty, and inform future regulatory developments for robot technology use and development at the European, National, Regional, or Municipal level (Fosch-Villaronga and Drukarch, 2020).

The LIAISON project brings into view the inconsistencies, dissonances, and inaccuracies of existing regulatory efforts and initiatives towards framing robot technologies. To this end, it focuses on personal care robots (ISO 13482:2014), rehabilitation robots (IEC 80601–2–78–2019), and agricultural robots (ISO 18497:2018), thereby aiming to uncover any gaps and inconsistencies and, additionally, gain insight into the usefulness and perceived value of the novel robot governance mechanism it introduces.

For this purpose, two feedback loops were created, namely for the purpose of assessing 1) regulatory gaps and inconsistencies in the relevant policy documents; and 2) the usefulness of LIAISON based on feedback from COVR Toolkit users and the broader community of stakeholders. The feedback loops depicted in figure 1 took the form of online surveys which were distributed across the networks built by the two major European networks on healthcare and agricultural robotics (the Digital Innovation Hub (DIH) on Healthcare Robots and the DIH on agricultural robots, from now on DIH HERO/DIH AGROBOFOOD), and were posted on social media platforms, including Twitter and Linkedin. Additionally, the call for participation was featured in the 'Exoskeleton Report'.[2]

To build the surveys, desktop research was conducted to investigate robots' safety compliance landscape, and the findings resulting from this research were refined through exploratory meetings and formal engagements with representatives from the industry, standardization organizations, and policymakers to present compliance tools as a potential source of data for policy purposes and action, and understand what information would be helpful to them. Moreover, to avoid low response rates and increase the focus of the obtained responses, the LIAISON project organised a set of interactive workshops, community engagement activities, and formal meetings which included the organisation of dedicated workshops and presentations at the online European Robotics Forum 2021[3] (13-15 April 2021), and the European Commission workshops on "Trends and Developments in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots" (2-3 March 2021), a set of dedicated webinars for the DIH HERO community[4], and several formal engagements with the respective DIH communities, the industry, academia, policymakers, and industry associations.

The data retrieved from the relevant surveys have been channeled to a so-called 'shared data repository,' currently comprising a comprehensive Google sheets file. This shared data repository will be made accessible to the relevant policymakers in due time. Any policy changes implemented on the basis of the shared data will, then, be presented in the COVR Toolkit as the presented standards, directives and regulations, allowing the envisioned iterative regulatory process for robot governance to restart.

4 Building a dynamic framework for evidence-based robot governance: key findings, lessons learned, & discussion

4.1 A mere website showing regulations is not enough help to robot developers comply

Robot manufacturers deal with many different legal frameworks, including standards and regulations. While compliance tools like the H2020 COVR Toolkit can help in this respect, the platform leaves room for desire: especially for new robot manufacturers, clarifying the applicable legal framework would help reduce the complexity in robot legal compliance. For instance, the COVR Toolkit does not distinguish between directives, which target EU member states and potentially lead to national legislation, and regulations, which are directly applicable. Furthermore, it does not explain the relationship between standards (usually non-binding) and the law (directives/regulation). Consequently, it is not clear what *binding* legal frameworks robot developers ought to comply with and which *recommended* frameworks concretize abstract legal principles.

[2] *See* https://exoskeletonreport.com/2021/03/liaison-seeks-feedback-on-exoskeleton-and-rehabilitation-robotics-standards/.

[3] *See* https://www.eu-robotics.net/robotics_forum/.

[4] E.g. a dedicated session on medical robot autonomy at MESROB 2021 which was held from 7-9 June 2021, and a dedicated presentation on gaps and inconsistencies in standards for personal care and rehabilitation robots at the DIH HERO Knowledge Conference 2021 which was held on 20 May 2021. Other engagements included a dedicated conference paper on LIAISON at the INBOTS conference 2021 which was held from 18-20 May 2021 and the COVR Open Day 2021 which was held on 3 June 2021.

Since current laws do not necessarily target specific types of robots, it is crucial to distill abstract standards into particular requirements capable of guiding developers in the development of a specific robot type. At present, the platform is limited to a small number of robot types and lacks a regulatory model personalized to each robot type, missing the opportunity to present developers with a clear picture of which laws apply to their robot technology. Logically, the platform is not intended to provide legal advice and may want to avoid any liability resulting from it.

In this vein, the platform is unidirectional: it merely presents legal information. This has the problem that, first, it needs to be updated and maintained with relevant developments. Most importantly, however, is that there is no engagement or feedback envisioned with the community. Following our engagement with the Digital Innovation Hubs - DIH-HERO and DIH-AgROBOfood, it became clear that LIAISON can strengthen the ecosystem created by these European initiatives by engaging them directly for governance purposes. Such an engagement could create a common platform to identify dissonances, and share lessons learned and tips from developers, which could be more valuable than a static information provision and allow developers to make their voice heard in robot governance activities (Fosch-Villaronga and Drukarch, 2021c). Over time, the generated knowledge could be helpful to policymakers to enact policies more attuned to stakeholder needs and rights. The importance and added value of combining the policy appraisal mechanism introduced through LIAISON with the COVR compliance tool has also been confirmed in the literature, which states that 'better tools and appraisal design can lead directly to better policy appraisal and hence better policies' (Adelle, Jordan and Turnpenny, 2012).

4.2 An ecosystem encompassing all stakeholder interests is lacking

It is noticeable that a common platform for channeling the interaction between public policymakers, standard organizations, robot developers/manufacturers, and end-users is currently lacking (Fosch-Villaronga and Drukarch, 2021c). The lack of a global ecosystem encompassing all stakeholder interests may entail many consequences. First, it prevents an active engagement with the affected stakeholders. For instance, ISO and standardization organizations alike welcome many stakeholders to participate in their standardisation activities but they do not proactively seek any stakeholder involvement e.g., they do not ask user groups to be involved. Over time, this creates power imbalances concerning the creation and production of norms geared towards framing robot development and user rights protection.

LIAISON highlighted how reshaping the mode of interactions yields helpful feedback from the community and thus facilitates the iterative regulatory process (Fosch-Villaronga and Drukarch, 2021c). It is thus essential to devise a mechanism for bringing together all stakeholders to align their efforts into making current and future robots safe to use. To create an optimal regulatory framework for new technologies, the European Commission needs to better communicate with society, standard-makers, and developers. A platform based on the model that LIAISON proposes could be beneficial in improving the communication between all stakeholders involved in the development and regulation (be it through public or private bodies) of new technologies.

4.3 Engaging with robot developers can generate policy-relevant knowledge

Engaging developers and end-users is instrumental in identifying unregulated and underestimated challenges (e.g., over-time integrative and adaptive systems' safety, cyber-physical safety, psychological harm) that regulatory frameworks should cover. These challenges arose in conversations with developers, and are mainly connected with the concerns and the challenges they find while turning a prototype into a marketable device. In this subsection, we introduce the different findings with respect to personal care, rehabilitation, and agricultural robots (Fosch-Villaronga and Drukarch, 2021b).

4.3.1. Findings concerning personal care robots

Personal care robot developers experience challenges and inconsistencies regarding ISO 13482:2014. While some developers perceive the standard as easy to follow and valuable as it is, others highlight that it could benefit from better guidance and that while useful, the standard could use different and more concrete examples and measures to be simpler and easier to follow. At the same time, the respondents indicate that the standard is clear concerning its language and layout. They nevertheless see room for improvement in the following sections: (i) safety requirements & protective measures, (ii) safety-related control system requirements, and (iii) verification and validation.

From the standard making side, in the exploratory meeting with a representative of the ISO Technical Committee TC299 (Robotics) Working Group 02 on Service Robot Safety standardization, working on the revision of ISO 13482:2014, it became evident that the TC299 sees potential areas for improvement of the standard in its scope and structure. A concrete example is the need to provide further guidance for specific user types. The importance of considering the elderly, children, and pregnant women under ISO 13482:2014 has been pointed out during the LIAISON workshop at the ERF, where participants generally indicated to believe that such consideration is fundamental. In this regard, the standard stated that the Working Group would revise the definition of personal care robots, taking into account concrete users such as children, elderly persons, and pregnant women. However, the 2020 revised standard shows no changes in this respect (Fosch-Villaronga and Drukarch, 2021a).

More specifically, participants indicated that the standard should consider concrete aspects for these different users: cognitive capabilities, different learning ways, safety, different limit values, mental and physical vulnerability, different body dimensions, interaction requirements, mental culture, physical disabilities, interaction with the robot, situation comprehension, body-reaction time, and size physiology. In addition, participants indicated that there should not be a simplification of specific user groups and standard revision within this context. Moreover, within this debate, the importance of adequate training was also stressed, thereby highlighting the need to reconsider the provided training that considers multiple user types.

Concerning the specific definition of personal care robot, LIAISON's methodology exposed problems associated with a lack of definition for *personal care* within the standard. Without a defined legal scope, engineers might comply with the wrong instruments (e.g., they might avoid medical legislation) and, therefore, be exposed to sanctions and further responsibilities. The LIAISON survey provided an example directed towards this, where a respondent indicated to be dealing with exoskeletons that fall under the physical assistant robots category but was uncertain as to whether she should follow the Medical Device Regulation (MDR).

Moreover, public responses during the ERF workshops indicate that those robot developers who have experience with ISO 13482:2014 run multiple standards for their devices. They also believe that their robot does not fit into the standard category, and they do not know if their robot is a medical device, and have all been confronted with different classifications from public and private policy documents. As a result of incorrect categorization and unclear classification, roboticists might put in place inappropriate safeguards, and users might be put in risky or harmful situations (Fosch-Villaronga, 2019).

In this sense, one of the most notorious confusing categories identified by developers through LIAISON when it comes to healthcare is whether a robot is a medical device or not. While ISO 13482:2014 aimed to bring more clarification to the field, it created many new confusing categories. The focus on personal care robots created an in-between category between service robots and medical devices. This ended up in two standards/categories: those for medical use and well-being and that personal care. However, the MDR states that "devices with both a medical and a non-medical intended purpose shall fulfill the requirements applicable to devices cumulatively with an intended medical purpose and those applicable to devices without an intended medical purpose" on its Art 1.3. This article was meant to avoid treating different devices that presented a similar risk to the user. For instance, colored contact lenses were considered cosmetics while presenting the same risks that contact lenses to replace glasses presented to the human eye. In this regard, the critical question is, to what extent will ISO 13482:2014 provide any room for those robotic devices that flirt the boundary of medical and non-medical.

While ISO 13482:2014 considers the consequences of error in robot autonomous decisions, the wrong autonomous decisions section only states, "a personal care robot that is designed to make autonomous decisions and actions shall be designed to ensure that the wrong decisions and incorrect actions do not cause an unacceptable risk of harm." However, the standard does not clarify the meaning of an "acceptable risk of harm" and a "non-acceptable risk," nor does it define the criteria to decide on this. Silence on these matters, however, does not provide a safeguard baseline.

Finally, as a solution, the standard states that "the risk of harm occurring as an effect of incorrect decisions can be lowered either by increasing the reliability of the decision or by limiting the effect of a wrong decision." This brings about the question whether a broader range of factors should be considered in the standard in this regard. For instance, it is not clear whether the provisions around safety as stipulated in the standard need to be combined with article 22 - on automated decision-making, including profiling - of the General Data Protection Regulation (GDPR). While the GDPR seems to have been drafted with computer systems in mind, cyber-physical systems have been primarily disregarded in this regard (Felzmann et al., 2018).

4.3.2. Findings concerning rehabilitation robots

Before rehabilitation robots can be made commercially available in the EU, manufacturers need to demonstrate that the device is safe. However, the safety validation of rehabilitation robots is complex. Especially when it comes down to straightforward testing procedures that can be used during robot development, information in regulations and standards is rare or scattered across multiple standards. This is partly because rehabilitation robots are relatively new, which reduces the availability of best practices and applicable safety standards.

Moreover, manufacturers of rehabilitation robots should be aware that article 1.6 of the MDR, in essence, states that devices that can also be seen as machinery (such as a robot) should also meet essential health and safety requirements as set out in Annex I of the Machinery Directive. Similarly, there might be standards from other domains which are more specific than the general safety and performance requirements listed in the MDR and can therefore be relevant for rehabilitation robots (e.g., personal care safety standards). However, the user must consider any restrictions or differences between the domains and be aware that the respective standard is not directly applicable (Bessler et al., 2021). Moreover, in the EU, the legislation for medical devices applies to rehabilitation robots. When a device complies with relevant so-called harmonized standards, the developer can assume that the device complies with the EU legislation. However, for medical devices, the current applicable harmonized standards are harmonized for the MDD. This means that between May 2021 and May 2024, there probably will be no or just a limited number of harmonized standards that can officially be used to demonstrate conformity with the MDR (Bessler et al., 2021). Important to note within this context is that the familiarization with applicable regulations and standards and the process of safety validation takes much time, which can be a burden, especially for small to medium enterprises and start-ups.

In addition to the documentation of the system and the risks involved, a validation of the risk mitigation strategies is also required. This validation is defined as a set of actions to evaluate with evidence that a bunch of safety functions meet a group of target conditions (Saenz et al., 2020) and is essentially a measurement to prove that a specific system complies with designated operating conditions characterized by a chosen level of risk. There is currently no guidance from standards on how validation measurements should be executed (Bessler et al., 2021). Especially concerning the usefulness of protocols[5], the majority of the participants in the LIAISON workshop at the ERF indicated that protocols offer a very clear and valuable tool in guiding them through the validation process.

4.3.3. Findings concerning agriculture robots

ISO 18497:2018 specifies principles for designing highly automated aspects of large autonomous machines and vehicles used for agricultural field operations but fails to include small autonomous agricultural robots into its scope. A regulatory framework for small autonomous agricultural robots is yet to be created. A valid question raised within this context relates to the definition the standard attributes to a highly automated agricultural machine - *does this definition also encompass agricultural robotic devices?* The insights provided by participants in the LIAISON workshop at the ERF led to interesting findings, with some participants believing that agricultural robots fall within the scope of this definition, and others thinking that they do not (*see* figure 2).

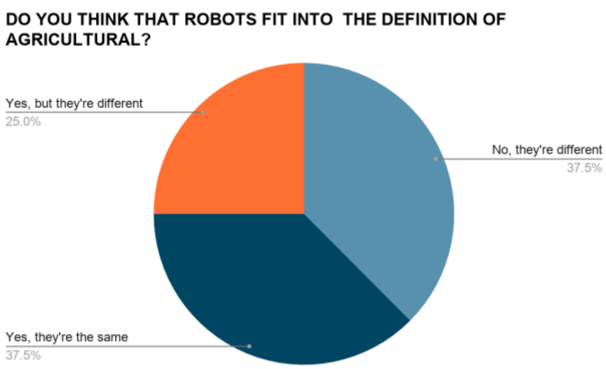
Engagement with DIH-AgROBOfood's standards work package leader led to the finding that no safety standard addresses agricultural robots during a rapidly advancing field. As a result, it will become necessary to specifically take this type of robotic field into account in the standard revision or create a standard tailored explicitly to agricultural robots.

[5] Protocols are step-by-step guides on how to validate safety of a robotic system. The validation relies on measurements, and the protocols will tell the robot developer how to conduct these measurements in a correct and reliable way.

On a European level, the Machinery Directive 2006/42/CE is the reference text on the regulation of equipment and machinery, including for agriculture. To observe these requirements, European and international norms and standards (EN and ISO) are applied. However, the emergence of agricultural robots have led to new functionalities and new applications and therefore unknown risks, which must be understood to best comply with the Machinery Directive. Compatibility with the automation of agricultural functions is not always apparent. The Directive stipulates that a machine must not make unexpected movements near a person. This calls into question the automated process that enables a robot to take over on start-up. Other discrepancies between text and practice include operator responsibility, mainly where the operator acts remotely.[6] Such operators are not always present with the robot but nevertheless may remain legally responsible for the safety of operations and must, therefore, be able to place the machine in safe mode at all times.

A key lesson learned from interacting with the agricultural community is that with risk analysis and the performance of tests and adjustments in the design phase, the key is developing reliable, safe machines within a regulatory context that is ill-suited and inaccurate.

Figure 2. Do you think that robots fit into the definition of agricultural machinery?



Therefore, within agriculture, harmonized standards from other sectors are applied analogously with agricultural robotics. On the remaining points, robot developers explain the risk analysis conducted and set out the solutions implemented in response, thereby demonstrating the resulting level of performance.

Finally, the involved Digital Innovation Hubs also stress this need for diverse stakeholder involvement. For instance, engagement with DIH AgROBOfood has presented the need for robot developers to pay attention to ethical, legal, and many other issues to determine if a robot will survive in a practical setting. Since agricultural robots barely interact with humans (at least not directly as in personal care or rehabilitation), the community is still not ready to engage with the ethical, legal, and societal (ELS) aspect community yet.

4.3.4. Cross-domain challenges

Safety standards are characterized by a 5-yearly revision, allowing for an evaluation of the adequacy of the relevant standard(s). Concerning the 5-yearly period for revision, the respondents to the LIAISON surveys and participants in the LIAISON workshop at the ERF presented clearly divided opinions on whether this timeframe is too long. Out of a pool of 15 respondents, 40% indicated that this timeframe is too long, while 60% disagreed with that opinion. These results were complemented with arguments from the workshop participants, stating that whether the 5-yearly revision is too long depends on the domain to which the standard relates - is the domain settled or still in the early stages of development? Moreover, it was argued that in some disciplines, there are still too few experts active in ISO, making it impossible to shorten the revision time frame. In addition, it takes time to gain sufficient experience in a particular domain to assess the adequacy of standards properly; revision should not be based on 'single-case experiences.' Moreover, it was argued that standards are supposed to offer a reliable framework for safety. By updating standards more frequently, we might risk undermining the reliability and dependability of standards.

While each of the investigated standards is concerned with physical safety requirements, the legislative system includes many other fundamental rights to be protected - e.g., 1) health, safety, consumer, and environmental regulations; 2) liability; 3) IP; 4) privacy and data protection; 5) capacity to perform legal transactions (Leenes et al., 2014). Concerning

[6] ISO 18497:2018 defines a *remote operator* as 'a human who is: 1) in primary control of a machine through the supervisory system; 2) receiving data for the purpose of supervising machine activity, and 3) is not on the machine but is located in the field, close to the field, or away from the field.

the adequacy of standards, the involved participants of the LIAISON workshop at the ERF believed that standards should shift from mono-impact to multi-impact, including factors related to ethics, environmental sustainability, liability, accountability, privacy, and data protection, and psychological aspects. As such, it is clear that robots, to be safe, need to comply with the safety requirements set by private standards and include other aspects highlighted within the law to ensure that the rights and protection of the user are not compromised.

The current cross-domain nature of robotics raises a dilemma for roboticists that many other users of the Machinery Directive and related harmonized standards do not encounter. This arises from the fact that the standards focusing on the safety of collaborative robotics are domain-specific, and it is not always clear to a roboticist which standards are applicable to their system. Currently, these standards covering different domains are not synchronized and can have conflicting requirements. This can lead to uncertainty, mainly when robots are used in new fields (such as agriculture) or for multiple domains (i.e., an exoskeleton used for medical purposes or to support workers in manufacturing) (Bessler et al., 2021).

A key cross-domain finding is that robots and AI technologies can impact humans beyond physical safety. Traditionally, the definition of safety has been interpreted to exclusively apply to risks that have a physical impact on persons' safety, such as, among others, mechanical or chemical risks. However, the current understanding is that integrating AI in cyber-physical systems such as robots, thus increasing interconnectivity with several devices and cloud services and influencing the growing human-robot interaction, challenges how safety is currently conceptualized rather narrowly (Martinetti et al., 2021). Thus, to address safety comprehensively, AI demands a broader understanding of safety, extending beyond physical interaction, but covering aspects such as cybersecurity (Fosch-Villaronga and Mahler, 2021) and mental health. Moreover, the expanding use of machine learning techniques will more frequently demand evolving safety mechanisms to safeguard the substantial modifications over time as robots embed more AI features. In this sense, the different dimensions of the concept of safety, including interaction (physical and social), psychosocial, cybersecurity, temporal, and societal, need to be considered for robot development (Martinetti et al., 2021). Revisiting these dimensions may help, on the one side, policy and standard makers redefine the concept of safety in light of robots and AI's increasing capabilities, including human-robot interactions, cybersecurity, and machine learning; and, on the other hand, robot developers integrate more aspects into their designs to make these robots genuinely safe to use.

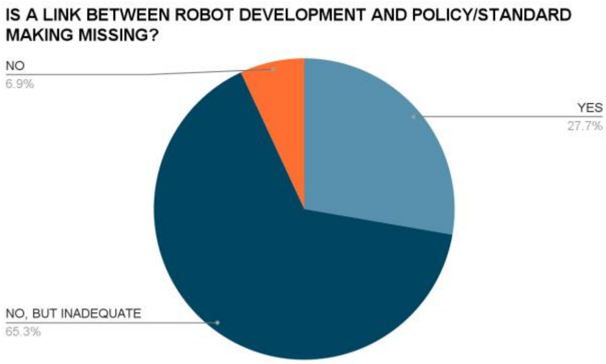
A final cross-domain challenge relates to the autonomy levels of robots. The levels of autonomy define the robot's progressive ability to perform particular functions independently. In other words, 'autonomy' refers to a robot's "ability to execute specific tasks based on current state and sensing without human intervention." For the automotive industry, the Society of Automotive Engineers (2020) established automation levels to clarify the progressive development of automotive technology that would, at some point, remove the human from the driving equation. However, no universal standards have been defined for progressive autonomy levels for personal care, rehabilitation, or agricultural robots.

Yang et al. (2017) proposed a generic six-layered model for medical robots' autonomy levels depicting a spectrum ranging from no autonomy (level 0) to full autonomy (level 5) to bridge this gap in the medical field. The effort is a significant step towards bringing more clarity to the field, especially with respect to the roles and responsibilities resulting from increased robot autonomy. Still, the model needs more detailing on how it applies to specific types of medical robots. Robots' embodiment and capabilities differ vastly across surgical, physically/socially assistive, or agricultural contexts, and the involved human-robot interaction is also very distinctive (Fosch-Villaronga et al., 2021).

4.4 A missing link between robot governance and development

The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF are very revealing. While 28% of the 27 respondents believe that currently there is no link between robot development and policy/standard making, 66% believe that such a link does exist but that this link is either too complex and lacks openness, merely far too complex or only exists between robot development and policy/standard making (Fosch-Villaronga and Drukarch, 2021c). This, while a small 7% of respondents believe that such a link already exists between robot development and policy/standard making.

Figure 3. Is a link between robot development and policy/standard making missing?



More specifically, in response to the question of whether a link between robot development and policymaking is currently missing, a range of responses was provided, namely 1) Yes, currently there is no such a link between robot development and policy/standard making (28%); 2) No, there is already such a link between robot development and policy/standard making, but it is too complex (38%); 3) No, there is already such a link between robot development and policy/standard making, but it is too complex and lacks openness (21%); 4) No, but the link is only between developers and standard organizations (7%); and 5) No, there is already such a link between robot development and policy/standard making (7%) (Fosch-Villaronga and Drukarch, 2021c).

4.5 The need for interdisciplinary cooperation

The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF indicate that for the regulatory approach proposed through LIAISON to be valuable and effective, a diverse group of stakeholders should be involved (Fosch-Villaronga and Drukarch, 2021c). These stakeholders include robot developers, manufacturers, policymakers, standardization organizations, legal scholars, and ethicists. The involved Digital Innovation Hubs also stress this need for diverse stakeholder involvement. For instance, engagement with DIH AgROBOfood has presented the need for robot developers to pay attention to ethical, legal, and many other issues to determine if a robot will survive in a practical setting.

In addition, the exploratory meeting with standard makers clarified the value of LIAISON in liaising standardization activities and robot development. More specifically, during one of the policy and standard-making institutional meetings, a representative of ISO Technical Committee TC299 (Robotics) Working Group 02 on Service Robot Safety standardization stressed establishing a relationship of cooperation between ISO/TC299/WG2 and LIAISON could be very useful and valuable. On the one hand, ISO/TC299/WG2 could provide LIAISON with the necessary input from standard making. On the other hand, looking at its goal, LIAISON could offer WG2 the relevant knowledge on inconsistencies and gaps in ISO 13482:2014 from the perspective of robot developers (Fosch-Villaronga and Drukarch, 2021d).

Moreover, the results obtained through the survey on the usefulness of LIAISON and the interactive sessions at the ERF also indicate that there is a serious need for cooperation between 1) central policymakers and standardization institutes; 2) major standardization institutes (ISO, BSI, CENELEC); and 3) user group initiatives and policy/standard makers.

4.6 Lack of legal comprehension

The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF indicate an overall lack in legal comprehension among robot developers, thereby adding emphasis to the first finding of a clear missing link between robot developers and policymakers. More specifically, the obtained data highlights this on three points: 1) experience with standards, 2) knowledge about the difference between public and private policymaking, and 3) experience applying standards. 23% of the 33 respondents indicated to have never used a standard before, against 77% who suggested having experience with standards (Fosch-Villaronga and Drukarch, 2021c). At the same time, while all respondents - based on a pool of 15 respondents - indicated being aware of and understanding the difference between standards and the law, approximately 33% showed to be still confused regarding this difference.

Interestingly, with regard to respondents' experience with standards - based on a pool of 26 respondents -, we were presented with a variety of responses, namely: 1) Run multiple standards for my devices (70%); 2) My robot does not fit into the standard category (45%); 3) Do not know if my robot is a medical device (40%), and 4) Do not know the difference between standard and regulation (10%).

It was indicated that smaller and younger companies often lack the necessary knowledge and understanding concerning the applicable legal frameworks and the difference between private and public policymaking within this context. Moreover, various meetings with the Digital Innovation Hubs DIH-HERO and DIH AgROBOfood have indicated this confusion among their community and the lack of legal comprehension. For this reason, these Digital Innovation Hubs stressed the value that LIAISON could also offer and the valuable insights that their community could provide policymakers in this respect. This has led to the organization of domain-specific webinars at a later stage in the LIAISON Research Project.

5 Conclusions

Based on the belief that the regulatory cycle is truly closed when it starts again upon the identification of new challenges, LIAISON puts the theoretical model of a dynamic, iterative regulatory process into practice, aiming to channel robot policy development from a bottom-up perspective towards a hybrid top-down/bottom-up model, leaving the door open for future modifications. As such, LIAISON aims to clarify what regulatory actions policymakers have to take to provide compliance guidance, explain unclear concepts or uncertain applicability domains to improve legal certainty and inform future regulatory developments for robot technology use and development at the European, National, Regional, or Municipal level. Moreover, by explicitly shedding light on the standardization activities in the abovementioned domains, LIAISON has created awareness about the barrier to access for robot developers and other relevant stakeholders concerning such activities.

Overall, LIAISON has proven to be a valuable tool to facilitate effective robot governance, as indicated by relevant stakeholders, because of its all-encompassing nature. Possible avenues for expansion relate to active involvement in standardization organizations, focus on harmonization activities, and legal and educational participation in Digital Innovation Hubs to create more legal awareness among the involved communities of robot developers. A platform based on the model proposed by LIAISON could be thus beneficial in improving the communication between all stakeholders involved in the development and regulation (be it through public or private bodies) of new technologies.

The results presented in this paper highlight the importance of and need for active stakeholder involvement in robot governance. However, currently, the link between robot development and policymaking is complex, and it lacks openness, transparency, and free access. Access to standardization activities is not always accessible due to high costs, and there is a lack of clarity concerning public policymaking activities and their relation to private standard making. This requires a reconsideration of how policy/standard makers engage with stakeholders in the normative process.

Moreover, the above results have indicated the need to seek active participation of affected parties (e.g., NGOs, user group initiatives - e.g., patients organizations and consumer networks -, and other interested groups). These parties should not only be involved at the end of the development and policy/standard-making chain. They form an integral part of the process and should be engaged in these activities from an early stage to provide input and feedback that will consider the needs and concerns of the wider public.

In the long-term, the expected project results may complement the existing knowledge on the 'ethical, legal, and societal (ELS)' of robotics by providing clarity on how to address pressing but still uncovered safety challenges raised by robots and represent a practical, valuable tool to advance social goals in a robotized workplace. Overall, advances in safety robot legal oversight will provide a solid basis for designing safer robots, safeguarding users' rights, and improving the overall safety and quality of efficiency delivered by robots.

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