H2020 COVR FSTP LIAISON – D2.4 Policy brief for standard and policymakers (EU & NEN)
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COVER

LIAISON

D2.4 Policy brief for standard and policy makers

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CONTENTS

SUMMARY

While robots should be safe, robot regulatory frameworks do not always frame technology development accurately. LIAISON investigates to what extent compliance tools, in this case, the COVR toolkit, could be used as data generators for policy and standard makers to unravel an optimal regulatory framing for existing and emerging robot technologies and improve robot technology overall safety and market entrance ease. As such, LIAISON aligns with the overall COVR goal to reduce complexity in safety certifying robots.

New technologies sometimes question and challenge existing norms, breathing into existence the need for legal change. While the pace of technology dramatically accelerates, however, legal responsiveness does not always follow as a consequent step. As no formal communication process between robot developers and regulators from which policies could learn has been established yet, a stepback mechanism for robot governance as novel as that introduced by LIAISON is yet to be introduced to all stakeholders involved, in particular robot developers and policy/standard makers. To prove the feasibility and added value of the creation of this link between robot developers and relevant regulators, for the LIAISON project, we focus on three particular standards: ISO 13482:2014 on personal care robots, IEC 80601-2-78:2019 on rehabilitation robots, and EN ISO 18497:2018 on agricultural machinery and tractors. The policy and standard makers involved for this purpose represent both private standardisation organisations and the European Commission.

This report presents the policy brief and leaflet for standard and policymakers which maps a set of policy recommendations for evidence-based policymaking for robot technologies, and provides related insights into gaps/inconsistencies in the relevant standards based on the findings obtained throughout the LIAISON project. Particularly, the presented policy brief and leaflet stress the importance of and the need for a reconsideration of how policy/standard makers involve and engage with stakeholders and affected parties within the context of the robot governance process, a careful review of the aspects taken into account in drafting new norms and regulations, and to gain a better understanding of what information standard/policymakers would consider valuable for robot governance purposes. Taking these and the other recommendations provided in this policy brief into account will help unravel an optimal regulatory framing for existing and emerging robot technologies, thereby improving robot technology's overall safety and market entrance ease. Finally, this report presents the dissemination of the presented policy brief and leaflet among the relevant standard/policymakers.

1. INTRODUCTION

COVR stands for "being safe around collaborative and versatile robots in shared spaces", and is a European H2020 Project which aims to reduce the complexity in safety certifying cobots significantly. In this respect, the project has developed the COVR Toolkit, an online tool that guides developers in their legal compliance process, from helping them find relevant technical standards/directives/protocols to guide them on performing a risk assessment.

Assessing risks through experimentation is essential to ensure robot safety and compliance with existing norms. However, standards do not always frame technology development accurately. LIAISON investigates to what extent compliance tools (tools that help comply with the legislation, such as the COVR toolkit) could be used as data generators for policy and standard makers to unravel an optimal regulatory framing (including change, revise, or reinterpret) for existing and emerging robot technologies. LIAISON is a crucial stepback mechanism to help align robot and regulatory development and improve robot technology's overall safety and market entrance ease. To prove the feasibility and added value of the creation of this link between robot developers and relevant regulators, for the LIAISON project, we focus on three particular standards: ISO 13482:2014 on personal care robots, IEC 80601-2-78:2019 on rehabilitation robots, and EN ISO 18497:2018 on agricultural machinery and tractors. The policy and standard makers involved for this purpose represent both private standardisation organisations and the European Commission. As such, LIAISON aligns with the overall COVR goal to reduce complexity in safety certifying robots by providing policy and standard makers with the necessary knowledge about legal inconsistencies, new categories, or new safety requirements (including psychological) to update existing frameworks where necessary and to ensure that the next generation of robots is 'safe' to the full extent of the word (*see* figure 1 in the annex). In this way, LIAISON contributes to the COVR mission by adding a link to public and private regulators to complete the cobot value chain.

To prove the feasibility and added value of creating this link between robot developers and relevant regulators, for the LIAISON project, we focus on three particular standards: ISO 13482:2014 on personal care robots, IEC 80601-2-78:2019 on rehabilitation robots, and EN ISO 18497:2018 on agricultural machinery and tractors. To ensure all parties are heard, LIAISON aims to include robot developers, policy and standard makers, and interested groups (e.g., ANEC). In this report, we present the policy brief and leaflet which include recommendations on evidence-based policymaking for robot technologies and the dissemination of the presented policy brief and leaflet among the relevant standard/policymakers. The policy brief comprises a more comprehensive insight into the policy recommendations derived from the work conducted throughout the LIAISON project, whereas the policy leaflet aims to provide a clear insight into the main recommendations and key findings.

2. LIAISON

2.1. BACKGROUND

"The art of progress is to preserve order amid change, and to preserve change amid order" – Alfred North Whitehead.

Robot technology is one of the many technologies that challenge the regulatory framework in various ways, including ethics and security for responsible innovation, privacy, and responsibility allocation. As products, robots widely differ in embodiment, capabilities, context of use, intended target users, and many regulations may already apply to them. Having tools such as the COVR Toolkit can be of help. However, new applications may not fit into existing (robot) categories, legislation might be outdated and confusing categories, and technology-neutral regulations may be hard to follow for developers concerned about their particular case. A recent open consultation launched by the European Commission, for instance, acknowledges that current European Harmonized Standards do not cover areas such as automated vehicles, additive manufacturing, collaborative robots/systems, or robots outside the industrial environment, among others (Spiliopoulou-Kaparia, 2017). In light of all the issues this technology arises, part of the literature accentuates the need for an issue manager. Marchant and Wallach (2015) proposed the creation of "Governance Coordinating Committees (GCC)" for the governance of emerging technologies like AI.

Furthermore, the European Parliament proposed creating a European Agency for Robotics and Artificial Intelligence early in 2017, and Schatz put forward the creation of an emerging technology policy lab within the US general services administration in 2018. However, what lacks in robot governance is a backstep mechanism that can coordinate and align robot and regulatory development (Fosch-Villaronga & Heldeweg, 2018). Overlooked in the latest review of "the grand challenges of science robotics," this challenge has already been raised in the literature, albeit only more recently (Yang et al. 2018), and relates to the idea of how policies can frame the rapid development of robotics. LIAISON contributes to these approaches by proposing the *modus operandi* of issue managers, if they were ever to exist, and revolves around the following main research question:

Could the use of compliance tools, such as the COVR Toolkit, as data generators for robot policy purposes reduce emerging robot governance complexity?

LIAISON envisions an iterative regulatory process for robot governance, a theoretical model that represents a practical step forward in the coordination and alignment of robot and regulatory development, called the Iterative Learning Governance Process (ILGP). This research project conceives an effective way to extract compliance and technical knowledge from compliance tools (tools that help comply with the legislation such as the COVR toolkit) and direct it to policy and standard makers to unravel an optimal regulatory framing (including change, revise, or reinterpret) for existing and emerging robot technologies. The primary outcome of the LIAISON Research Project will be the design concept for liaising robot development and policymaking to increase overall robot safety. This design concept will further develop the *Iterative Regulatory Process for Robot Governance*, which was ideated as a theoretical model that links technology impact assessments to legislative ex-post evaluations via shared data repositories intending to create evidence-based policies that can serve as temporary benchmark for future and new uses or robot developments (Fosch-Villaronga & Heldeweg, 2018, 2019). Part of the 'technical challenge' is to put such a theoretical model into practice and in the context of the COVR project. Explained further in figure 2 (annex) such iterative regulatory process for robot governance stresses that in the light of a new robot development or use, and after assessing all the impacts (and incorporating the findings into the robot itself), it is essential to compile all the Regulation-to-Technology uncovered barriers and constraints that do not allow the roboticists to proceed with their creation. Having collected those constraints in a Technology-to-Regulation manner, the regulator can act thereupon supported by the accountability tool's information, in this case, the COVR Toolkit.

2.2. APPROACH

Seeing regulation (broadly understood) as a tool to advance social goals and subject to adjustments towards this end, LIAISON discusses different regulatory approaches to use iterative governance processes for robot governance. For that purpose, LIAISON aims to engage with representatives from the industry, standardization organizations, and policymakers to present compliance tools as a potential source of information for policy action and understand what information would be helpful to them (e.g., through exploratory meetings, surveys, and workshops). Applying such a novel and interdisciplinary methodology is instrumental in identifying unregulated and underestimated challenges (e.g., over-time integrative and adaptive systems' safety, cyber-physical safety, psychological harm) that regulations should cover, and in gauging the response to, support for, and perceived necessity among relevant stakeholders of the introduction of the LIAISON model.

Following the ideal that lawmaking 'needs to become more proactive, dynamic, and responsive,' LIAISON proposes the formalization of a communication process between robot developers and regulators from which policies could learn, as depicted in figure 1 (annex), thereby channeling robot policy development from a bottom-up perspective towards a hybrid top-down/bottom-up approach. This is novel, as most approaches have been top-down solely, disregarding the richness field knowledge could provide in helping identify gaps and inconsistencies in frameworks governing the technology. In practice, LIAISON builds on the COVR toolkit, a compliance tool built as part of the COVR Project, by envisioning and assessing the usefulness of the proposed model based on the theoretical model of an *Iterative Regulatory Process for Robot Governance*. Following through the COVR Toolkit in the capacity of a robot developer, the Toolkit offers a section on standards and directives, allowing robot developers to filter their search results based on domain and appearance. The Toolkit then presents the relevant regulations, directives, and standards which can be freely accessed or purchased by robot developers. After robot developers have assessed the relevant documents, LIAISON enters into the picture. Focussing specifically on standards in 3 domains of application (rehabilitation, personal care, and agriculture), LIAISON aims to uncover the gaps and inconsistencies in the relevant policy documents. For this purpose, we have created two feedback loops to assess 1) regulatory gaps and inconsistencies in the relevant policy documents; and 2) the usefulness of LIAISON based on Toolkit user feedback and the broader community of stakeholders. To this end, we created a survey to match each feedback loop and distributed these among a predetermined pool of stakeholders through various means and on a variety of platforms.

Concerning the first feedback loop, assessing the identified gaps and inconsistencies in the relevant policy documents was refined through a set of interactive workshops, community engagement, and formal meetings. The data retrieved from these surveys have been channeled to a so-called 'shared data repository,' currently comprising a comprehensive Google sheets file. This shared data repository will be accessible to policymakers in due time, who are encouraged to use the relevant data to change, revise, or reinterpret existing frameworks. Once again, these will be presented in the COVR Toolkit, allowing the iterative regulatory process for robot governance to restart.

2.3. GOALS

We believe that the regulatory cycle is truly closed when it starts — or allows it to be started — again upon new challenges/technologies. LIAISON tests the theoretical model of a dynamic, iterative regulatory process in practice, aiming to channel robot policy development from a bottom-up perspective towards a combined top-down/bottom-up model, leaving the door open for future modifications. The above-envisioned process will 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. Within this regard, LIAISON takes the lead in tackling the existing regulatory challenge, thereby linking robot development and policymaking to reduce the complexity in robot legal compliance. Moreover, by explicitly shedding light on the standardization activities in the abovementioned domains, LIAISON aims to create awareness about the barrier to access for robot developers and other relevant stakeholders concerning such activities.

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.

3. POLICY BRIEFS

- PLEASE FIND A COPY OF THE RELEVANT ATTACHMENTS IN THE ANNEX -

4. REFERENCES

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5. ANNEX

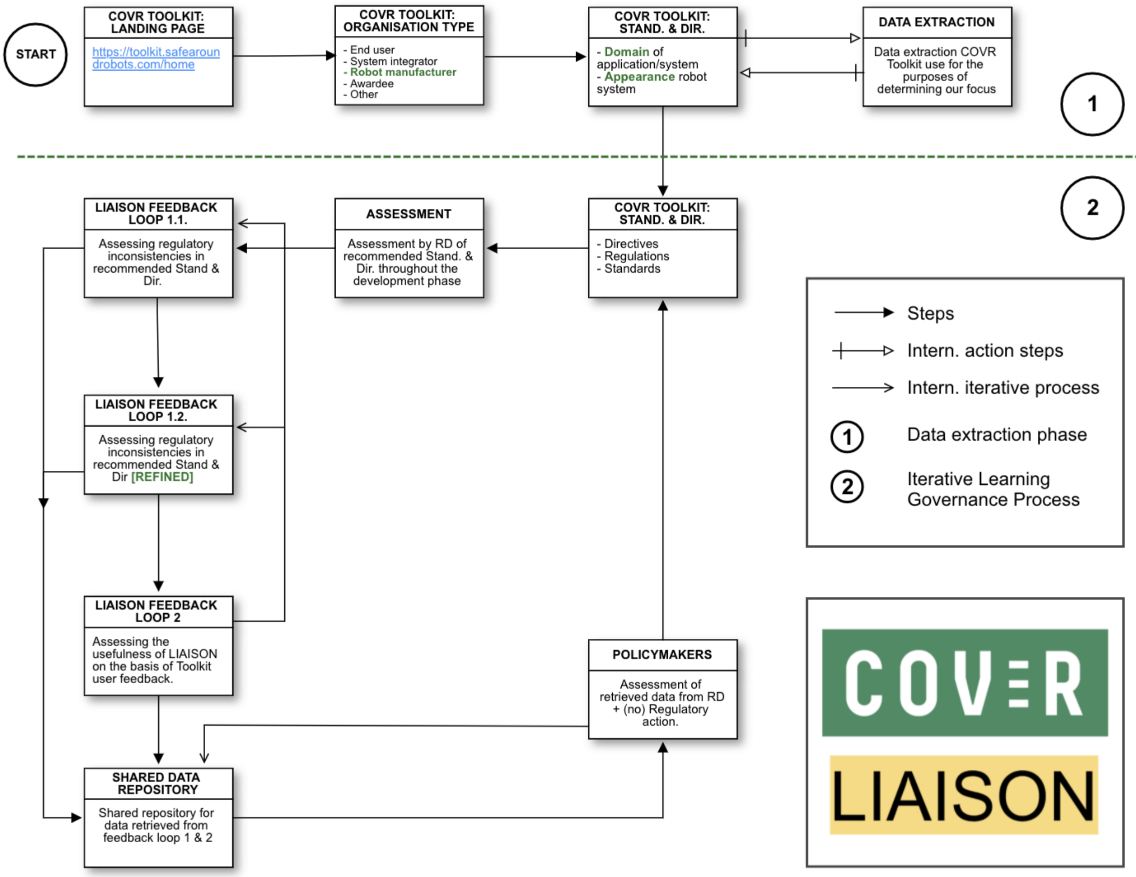

Figure 1: LIAISON Research Project mechanism

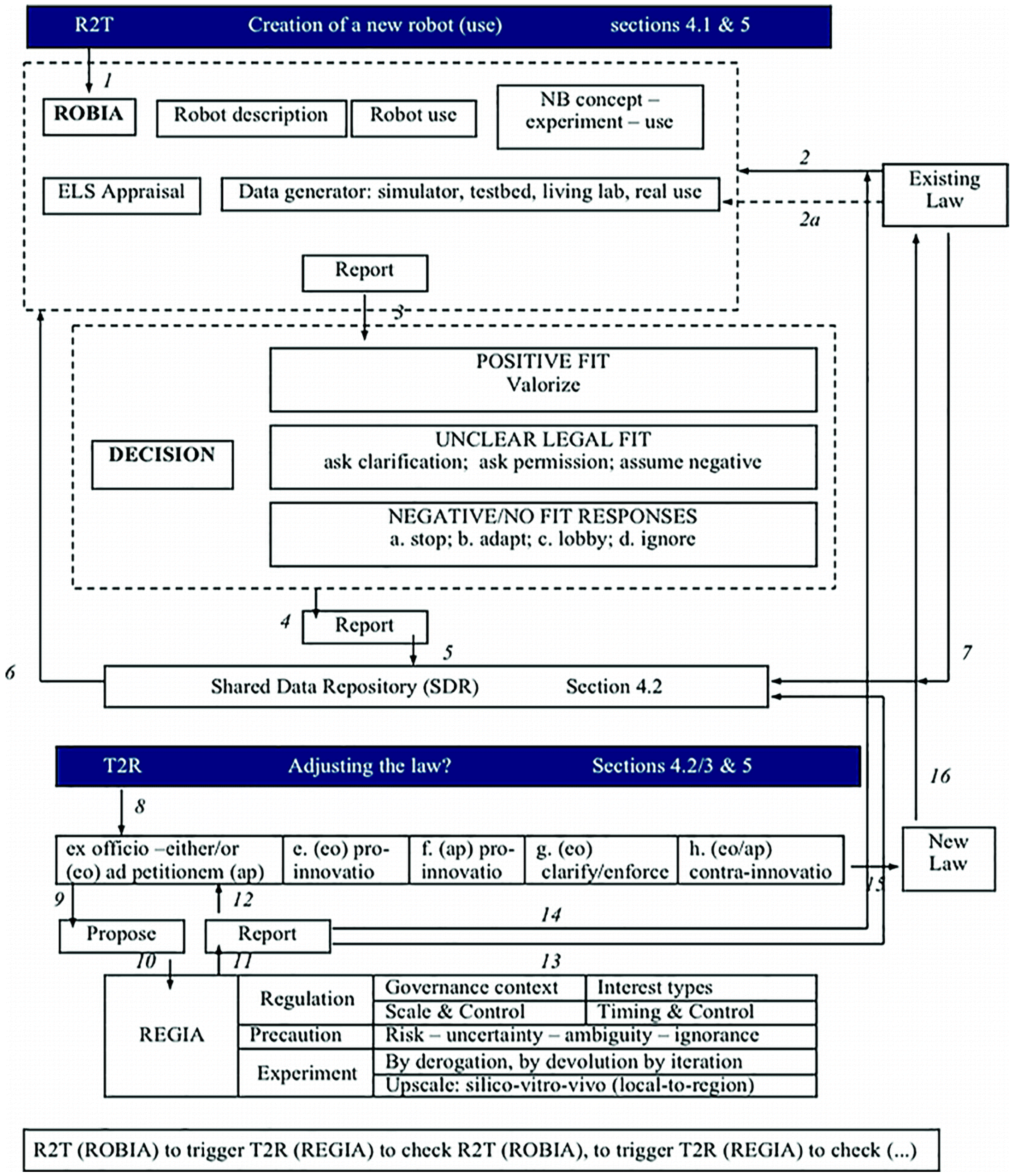

Figure 2: Preliminary iterative process for robot governance[1] (Fosch-Villaronga & Heldeweg, 2018).

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[1] As regards the meaning of arrows: #1. signifies that upon the initiative to develop a new robot (use) the ROBIA process commences; #2 and #2a are about information about existing law/legal space being fed into the ROBIA fit to regulation process; #3 outcomes of ROBIA are reported to initiators to decide if and if so, how the development process can be continued; #4 and #5 concern reporting the decision and making information available to the SDR system; #6 is about how (changes in) information in SDR are a source of information to the ROBIA process – as shared learning; #7 is about information about existing law with relevance to robotics is also part of the shared date in SDR (#2 is about specific legal information to a specific ROBIA procedure; #7 about the general updating of legal info in SDR); #8 expresses that upon R2T events a process about possible legal adjustments is started; #9 and #10 when it is decided (ex officio/ad petitionem) that some legal change may be called for, a (basic) proposal is formulated whereupon the REGIA procedure is initiated; #11 and #12 show that outcomes of the REGIA procedure are reported back and feed into the decision on legal change; #13 Information in the report is also fed into SDR to update regulatory information; #14 REGIA report can feed ROBIA without passing via the Existing law> box, as the REGIA report will say something about pros and cons of possible legal change, but should that change follow, then this will communicate via the <New law> box; #15 signifies adjustments in the law; #16 expresses that new law changes and becomes part of existing law.)

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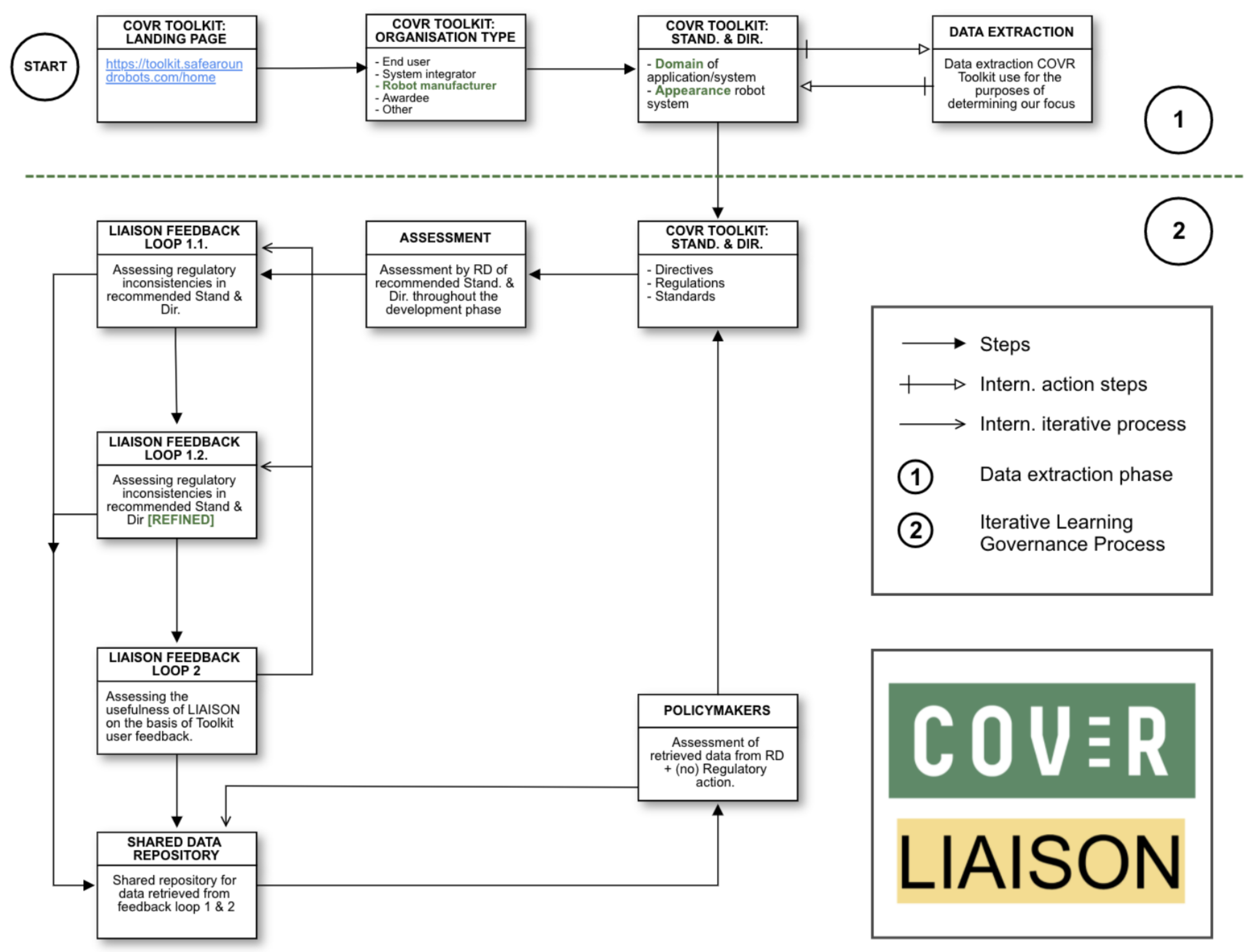
Policy Brief on Evidence-Based Policymaking for Robot Technologies

The complexity of robot governance

- Technology and regulation evolve, but **not always simultaneously or in the same direction**.
- Robot developers **struggle to find suitable safeguards in existing norms applicable to them**.
- The robot governance ecosystem **lacks a common platform for all stakeholders to share and learn**.

The LIAISON project

- **Links robot development and policymaking** to reduce the complexity in robot legal compliance.
- Creates a **communication platform** between robot developers and regulators.
- Investigates whether **compliance tools can serve as data generators for robot governance purposes**.



Findings

- An ecosystem encompassing all stakeholder interests is lacking.
- Engaging with robot developers can generate policy-relevant knowledge.
- Standards covering different domains are not synchronized and can have conflicting requirements.
- No universal standards have been defined for progressive autonomy levels for personal care robots, rehabilitation robots, or agricultural robots, raising serious concerns about responsibility allocation.
- To be safe, robots 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.
- Safety dimensions include interaction (physical and social), psychosocial, cybersecurity, temporal, and societal.
- Robots and AI technologies can impact humans beyond physical safety.
- Policymaking should be fuelled by a cross-domain and multi-stakeholder approach.

Takeaways

- Active **stakeholder involvement in robot governance is crucial and needed**.
- **LIAISON could be a valuable tool to facilitate effective robot governance** because of its all-encompassing nature.
- Advances in robot legal oversight provide a solid basis for designing **safer robots, safeguarding users' rights, and improving the overall safety and quality of care**.

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Policy Brief on Evidence-Based Policymaking for Robot Technologies

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Executive summary

Although technology and regulation evolve, they do not always do so in the same direction. 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. Following the ideal that lawmaking 'needs to become more proactive, dynamic, and responsive,' LIAISON proposes the formalization of a communication process between robot developers and regulators from which policies could learn, thereby channeling robot policy development from a bottom-up perspective - which has traditionally been the approach followed in judicial analysis - towards a hybrid top-down/bottom-up approach. To this end, LIAISON investigates to what extent compliance tools, such as the COVR Toolkit, could serve as data generators for emerging robot governance purposes, thereby taking the domains of personal care robots (ISO 13482:2014), rehabilitation robots (IEC 80601–2–78–2019), and agricultural robots (ISO 18497:2018) as case studies. As such, LIAISON is taking the lead in tackling the existing regulatory challenge, thereby linking robot development and policymaking to reduce the complexity in robot legal compliance.

This policy brief provides policy recommendations to better approach evidence-based policymaking for robot technologies. In particular, it stresses the importance of and the need for a reconsideration of how policy/standard makers involve and engage with stakeholders within the context of robot governance process, as the link between robot development and policymaking is currently perceived as complex and lacking openness, transparency, and free access. Moreover, it highlights the need to seek active participation of affected parties, which form an integral and non-neglectable part of the governance process and should therefore not only be involved at the end of the development and policy/standard-making chain but also at the early stages to provide input and feedback that will consider the needs and concerns of the wider public. Taking these and the other recommendations provided in this policy brief will help unravel an optimal regulatory framing for existing and emerging robot technologies.

Acknowledgment

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Disclaimer

Introduction

New technologies offer possibilities until recently unimaginable and can solve problems faster, better, and more efficient 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 & Heldeweg, 2018). Yet, while the development of new technologies rapidly accelerates, there is an increasing gap between the policy cycle's speed and that of technological and social change (Sucha & Sienkiewicz, 2020). An understanding of technology's implications and consequent assessment and legal responsiveness do thus not always follow suit (Marchant, 2011; Newlands et al., 2021). This gap is especially becoming broader and more prominent in robotics (i.e., movable machines that perform tasks either automatically or with a degree of autonomy) - and especially in the field of healthcare robots (Fosch-Villaronga, 2019) -, since current legislation was clearly unprepared to address the implications of machine learning and autonomous agents and, as a result, often lags and does not adequately frame robot technologies.

This state of affairs inevitably increases legal uncertainty as 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. Moreover, inserting robot technologies capable of replacing tasks previously carried out by humans fundamentally changes previously held roles and responsibilities and questions the suitability of existing laws in this regard. A clear example of this can be found in the area of surgery automation. While surgeries have traditionally been performed by human surgeons and their staff, nowadays autonomous surgical robots increasingly are put to use to help human surgeons perform such procedures (Yang et al., 2017). The new ecosystem that is formed because of this involves different actors among which the hospital and the manufacturer, various degrees of robot autonomy, and an adaptive role of humans to surgery automation. Such a complex ecosystem complicates our ability to understand where faults or errors originated, determine causality, and attribute responsibility, especially if there is no clear regulatory guidance in this regard (Fosch-Villaronga et al., 2021).

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 poses an immense challenge for how robot developers integrate legal considerations into their design to make robots safe (Holder et al., 2016; Fosch-Villaronga, 2019).

Besides, while current legal frameworks mostly focus on physical safety, in practice robots interact with humans in various ways, including socially, raising other questions than mere those related to physical safety (Martinetti et al., 2021). Consequently, current developments fail to provide an adequate level of safety and do not perform well in the wild (Gruber, 2019), calling into existence 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 & Heldeweg, 2018).

In response to this mismatch, some European projects have created different compliance tools (i.e., online tools that help comply with existing legislation). An example of such a tool is the COVR toolkit, which was developed by the H2020 COVR project, a project which stands for 'Being safe around collaborative and versatile robots in shared spaces.' The COVR 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. To this end, the COVR project presents detailed safety assessment instructions to coboteers and makes the safety assessment process clearer and simpler, which, in turn, allows for a more trustworthy and responsible use of cobots in society.

Although compliance tools, such as the COVR Toolkit, certainly may be helpful to robot developers in their efforts towards robot legal compliance, new applications may nevertheless fail to fit into existing (robot) categories. Besides, regulatory frameworks resulting from both private and public policymaking activities (Winfield, 2019) are possibly outdated, might contain confusing categories, or may be technology-neutral making it hard to follow for developers who are concerned about their particular work (Fosch-Villaronga, 2019). In this sense, compliance tools are unidirectional and top-down while robot developers, in complying with existing legal frameworks, may well find mismatches and dissonances relevant to policymakers. Channeling robot policy development from a bottom-up perspective towards a combined top-down/bottom-up model might thus offer new and valuable perspectives within the context of robot governance.

Bearing this in mind, the LIAISON project, a subproject from the H2020 COVR project, 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 (*see* figure 1). 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 & Drukarch, 2020). As such, LIAISON is a crucial stepback mechanism to help align robot and regulatory development and improve robot technology's overall safety and market entrance ease.

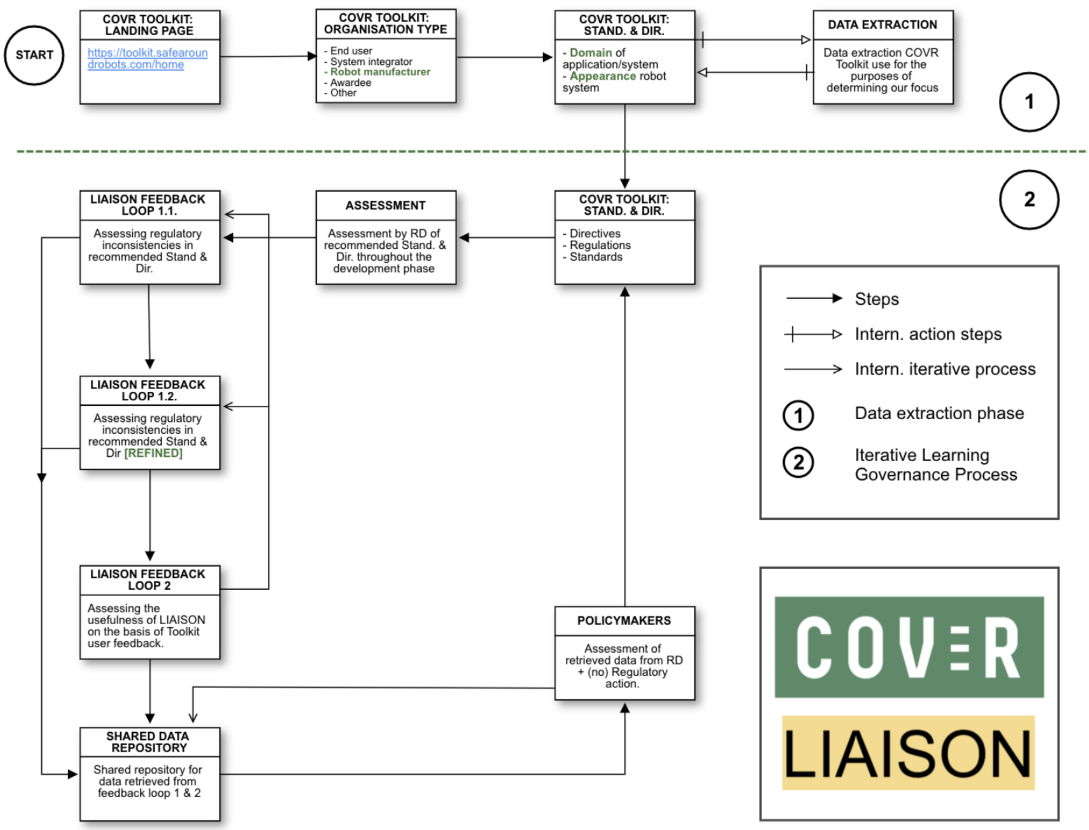

Figure 1: LIAISON Research Project mechanism

To test the theoretical model for an iterative regulatory process for robot governance in practice, LIAISON focuses on personal care robots (ISO 13482:2014), rehabilitation robots (IEC 80601–2–78–2019), and agricultural robots (ISO 18497:2018). This policy brief presents a set of policy recommendations for evidence-based policymaking for robot technologies, and provides related insights into gaps/inconsistencies in the relevant standards based on the findings obtained throughout the LIAISON project.

Recommendations

1 | 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. There are mechanisms to connect some of the stakeholders, but there is no global ecosystem encompassing all the interests. Not having an ecosystem entails 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 has highlighted how reshaping the mode of interactions yields helpful feedback from the community and thus facilitates the iterative regulatory process for robot governance. For instance, the interaction between developers and policymakers should be built around group interaction and discussion rather than through surveys and consultations, which leads to a low response rate, particularly from the community of robot developers.

LIAISON addressed this limitation by organizing a set of interactive workshops involving the DIH HERO and DIH AGROBOFOOD communities.

It is thus essential to devise a mechanism for bringing in all these stakeholders together and align their interests into making current and future robots safe. 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 proposed by LIAISON 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.

2 | Engaging with robot developers can generate policy-relevant knowledge

Engaging robot 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. Through its contacts with developers, LIAISON was able to unearth several instances of policy-relevant knowledge. These issues arose in conversations with developers.

As such, they are mainly connected with their concerns and the challenges they have found while turning a prototype into a marketable device. In the following, we introduce the different findings with respect to personal care, rehabilitation, and agricultural robots.

Personal care robots

Personal care robot developers experience challenges and challenges and inconsistencies regarding ISO 13482:2014. The respondents have varying experiences with the standard. Some developers perceive it as easy to follow and valuable as it is. Others highlight that the standard could benefit from better guidance and that while useful, the standard could use different and more concrete examples and measures to be easier to follow. At the same time, the respondents indicate that the standard is either moderately or very clear concerning its language and layout. They nevertheless see room for improvement in the following sections: safety requirements & protective measures, Safety-related control system requirements, and 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 & Drukarch, 2021). 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 also 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) as well.

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, 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 for 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).

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 1.3 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 Medical Device Directive. 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, the majority of the participants in the LIAISON workshop at the European Robotics Forum (ERF) indicated that protocols offer a very clear and valuable tool in guiding them through the validation process.

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.

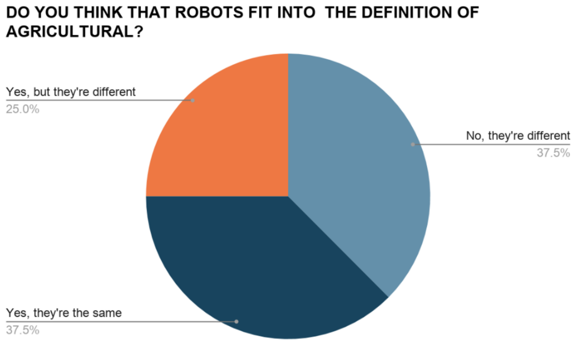

Figure 2. Do you think that robots fit into the definition of agricultural machinery?

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. 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 problem is developing reliable, safe machines within a regulatory context that is ill-suited and inaccurate. 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.

Additionally, measuring and characterizing harsh climatic conditions is very challenging. There are no requirements in ISO 18497:2018 and other norms applicable to detection systems in climatic conditions. Some norms are under definition by the World Meteorological Organization, offering a possible point of reference within the context of this standard. Moreover, ISO 18497:2018 lacks clarity in distinguishing between sensitive and non-sensitive sensors. This is important as it determines the extent to which direct contact is or is not allowed and the criteria that apply within this context.

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.

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). This highlights that mono-impact standards, e.g., focusing on physical safety, may not offer users enough protection. Concerning 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. This further indicates the need for a multi-disciplinary multi-stakeholder approach. 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 & 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).

3 | LIAISON model usefulness

While LIAISON's exact usefulness and feasibility from the perspective of standardization is difficult to express at this current stage, both robot developers and policymakers believe that the governance model proposed by LIAISON can significantly contribute to reducing the complexity in robot governance and robot legal compliance in the long term. In this section, we present some findings with respect to the usefulness of the LIAISON model.

Confirming the missing link between policymaking and robot development

The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF are very revealing (see figure 3). 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 far too complex, too complex and lacks openness, or only exists between robot development and policy/standards making. This, while a small 7% of respondents believe that such a link already exists between robot development and policy/standard making.

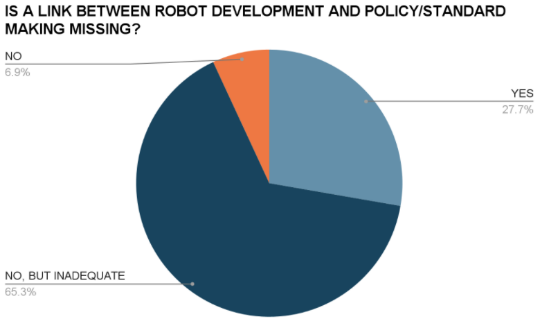

Fig. 3 Is a link between robot development and policy/standar making missing?

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 see figure 3), 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%).

Acceptability and perceived usefulness

With regard to the feasibility, usefulness, and acceptability of LIAISON from the perspective of standard making and standard makers, the exploratory meetings with relevant policy/standard makers indicated that within the context of robot regulation, there is a large ecosystem involving public policymakers (link: harmonization), standard organizations (link robot developer/safety), robot developers/manufacturers, and end-users, which is not sufficiently aligned.

Furthermore, concerning the exploratory meetings with relevant policymakers, the above finding indicated the importance of bringing together all stakeholders to align their efforts into making current and future robots safe to use. In addition, these exploratory meetings led to the finding that while LIAISON's exact usefulness and feasibility from the perspective of standardization is difficult to express at such an early stage, it is clear that LIAISON can be beneficial in certain regards. Robot manufacturers have a set of many standards that they use in developing and manufacturing their products. Together, these standards will cover all regulations, but each one individually covers only a part. As robot manufacturers ought to prove that they are compliant with each applicable standard, they need to know which standards apply to their products. Especially for new robot manufacturers (a more specific version of), the COVR Toolkit could be helpful and valuable. LIAISON can also add to this by providing a mechanism for improved and continuously improving robot regulation.

Finally, following our engagement with the relevant Digital Innovation Hubs, it became clear that LIAISON is a highly relevant initiative from Digital Innovation Hubs' perspective especially considering their focus on standardization work activities led by their respective work packages. 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 where lessons learned are shared and, in this way, simplify existing complex procedures for having the voice heard of a particular stakeholder. Over time, the generated knowledge could be helpful to policymakers to enact policies more attuned to stakeholder needs and rights.

D***iversity and multi-impact standards***

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. These stakeholders include robot developers, manufacturers, policymakers, standardization organizations, legal scholars, and ethicists. For instance, 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. This further indicates the need for a multi-disciplinary multi-stakeholder approach.

As presented above, respondents have indicated the need for stakeholder involvement in LIAISON. However, respondents also stress the need for cooperation among different stakeholders. The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF, based on the responses of a pool of 13 respondents, show 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.

The need for interdisciplinary cooperation

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.

Moreover, engagement with the Digital Innovation Hubs DIH-HERO and DIH-AgROBOfood has brought forward the finding that it would be valuable for these Digital Innovation Hubs and LIAISON to strengthen further cooperation and collaboration for the overall benefit of robot governance. For this reason, both Digital Innovation Hubs offered to contribute to the goals and objectives of LIAISON and opened up the discussion for potential future funding for this and similar initiatives.

Lack of legal comprehension

The results gained from the survey on the usefulness of LIAISON and the interactive sessions at the ERF indicate an over 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. 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%).

Finally, 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 project.

Conclusion

Based on the belief that the regulatory cycle is truly closed when it starts - or allows it to be started - again upon new challenges/technologies, LIAISON put 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. Within this regard, LIAISON is taking the lead in tackling the existing regulatory challenge, thereby linking robot development and policymaking to reduce the complexity in robot legal compliance. 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.

The results presented in this policy brief stress 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 recommendations highlight 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 non-neglectable 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.

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. 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. 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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