COVER

LIAISON

D1.1 Report on safety standards' uncovered challenges

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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 put into 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 robot developers and policy/standard makers. 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.

In this report, we cover safety standards' uncovered challenges. More specifically, we present the regulatory inconsistencies and challenges in existing standards in the field of personal care robotics (ISO 13482:2014), rehabilitation robotics (IEC 80601-2-78:2019), and agricultural machinery and tractors (ISO 18497:2018) as identified through desktop research and complemented with feedback obtained from relevant stakeholder communities through a set of dedicated feedback surveys, interactive workshops, community engagement, and exploratory meetings. As such, this report brings together existing knowledge on uncovered challenges in the relevant robot regulatory frameworks and practical experience from the broader community of stakeholders (including, but not limited to, robot developers, policymakers, and academia, and interested groups) within this regard. The findings in this report generally indicate that while standardization activities have shown outstanding effort into creating a safety framework for the relevant robots, they require careful evaluation, review, and multi-stakeholder collaboration to offer optimal and more future-proof protective framework for user protection. LIAISON aims to contribute in this regard by mapping legal inconsistencies and challenges in the relevant standards with the help of relevant stakeholders and liaising robot development with policymaking by channeling these findings to the relevant 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 guiding them on how to perform 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. 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. 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 identify inconsistencies, confusing categories, and uncovered challenges in EU legislation and safety standards, a set of feedback surveys, linked to each of the standards that are the focus of the LIAISON Research Project, was drafted and distributed among an established pool of robot developers active in the relevant fields of application (i.e., personal care robotics, rehabilitation robotics, and agricultural robotics). In this report, we present the regulatory inconsistencies and challenges in existing standards in the field of personal care robotics (ISO 13482:2014), rehabilitation robotics (IEC 80601-2-78:2019), and agricultural machinery and tractors (ISO 18497:2018). We identified these through desktop research and complemented them with feedback obtained from relevant stakeholder communities through the above feedback surveys and interactive workshops at the European Robotics Forum (ERF), community engagement, and exploratory meetings. This report sets the scene in section 2 with an overview of LIAISON's background, methods, goals, and objectives. Section 3 provides an overview of the methods utilized to map the inconsistencies, confusing categories, and uncovered challenges in the relevant EU legislation and safety standards. Section 4 elaborates on the landscape of EU legislation and safety standards - highlighting the difference between public and private policymaking, harmonization, and the robot regulatory frameworks that focus on this research. In section 5, we map the inconsistencies and challenges that the relevant robot regulatory frameworks present. Finally, we conclude in section 6.

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 1, 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 2 (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. METHODS

3.1. METHODS

Several methods were utilized to identify and map inconsistencies, confusing categories, and uncovered challenges in the above robot regulatory frameworks, namely desktop research, surveys, workshops, community engagement, and exploratory meetings. Below, these methods are further elaborated.

3.1.1. DESKTOP RESEARCH

LIAISON aims to uncover the gaps and inconsistencies in the relevant policy documents. For the purposes of this contribution, we conducted a desktop research and literature review. We reviewed existing research on and evaluations of the relevant safety standards. These sources include research articles, web pages, and product catalogs, retrieved from online academic databases and web search results on Google and Google Scholar. The findings derived from this desktop research forms the basis of this report and are further complemented and validated by responses and practical experience from the broader community as derived from the methods described below.

3.1.2. SURVEYS

To identify and map existing inconsistencies, confusing categories, and uncovered challenges in ISO 13482:2014 (on personal care robots), IEC 80601-2-78:2019 (on rehabilitation robotics), and ISO 18497:2018 (agricultural machinery and tractors) as experienced by the wider community of stakeholders, we created three surveys to match the first feedback loop (see figure 2, annex). To avoid having a low response rate from robot developers as announced by some of the relevant policymakers in our formal meetings (*see* D1.3) and also increase the focus of the responses, LIAISON engaged with two major European networks on healthcare robotics (the Digital Innovation Hub (DIH) on Healthcare Robots[1] and the Digital Innovation Hub on agricultural robots,[2] from now on DIH HERO/DIH AGROBOFOOD) (*see* further below in section 3.1.4). We distributed these surveys among the predetermined pool of stakeholders from the DIHs and the H2020 COVR Project, including several dedicated emails to their networks, and on a variety of platforms (including Twitter, Linkedin, and stakeholder websites.[3]

These feedback surveys cover a general assessment, including usability and satisfaction, and language and layout; and an evaluation of specific topics, focussing on experienced inconsistencies and incompleteness in the relevant standards; and leaves room for concerns, improvement, and feedback. The links to these surveys can be found in the table below.

[1] *See* https://dih-hero.eu/.
[2] *See* https://agrobofood.eu/.
[3] E.g., see here for collaboration with DIH-HERO, here for collaboration with DIH-AgROBOfood, and here for collaboration with COVR.

LIAISON SURVEYS		
SURVEY	**URL**	**OVERVIEW**
ISO 13482:2014	CLICK HERE	CLICK HERE
IEC 80601-2-78:2019	CLICK HERE	CLICK HERE
ISO 18497:2018	CLICK HERE	CLICK HERE

3.1.3. WORKSHOPS

3.1.3.1. WORKSHOP EUROPEAN COMMISSION

In continuation of the exploratory meeting with representatives of the European Commission, we attended the European Commission workshops "Trends and Developments in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots" to present the LIAISON Research Project.[4] These workshops were part of the Study on Trends and Development in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots Controlled by Artificial Intelligence currently conducted by the European Commission. The workshops were envisioned to gather feedback from the involved stakeholders on the results from various project tasks and the conducted interviews, analyze the stakeholder's (potentially conflicting) position, and incorporate the lessons learned in the final study report.

We were invited to present the LIAISON Research Project, participate in the ongoing discussion, and exchange thoughts and ideas on (tackling) gaps and inconsistencies in existing technology regulatory frameworks. The workshops focussed, among other things, on the domains of healthcare and agriculture. For an overview of the workshop timetable, see table 1 (annex).

The results from this workshop have shown how important it is to have a mechanism that could align the different stakeholders linked in robot development. While there is currently a link between some of the stakeholders, the process is very complex, and its intricate inner workings prevent the free access and participation of key affected stakeholders, which is not desirable from public policymaking.

3.1.3.2. ERF WORKSHOP

As part of the ERF 2021, LIAISON was part of two workshops throughout the event - a guest presentation at the DIH-HERO workshop op Robotics in healthcare: Future perspectives[5], and the hosting party at the workshop on LIAISON: Liaising robot development and policy making.[6] The latter comprised an interactive webinar to gain an insight into the challenges that the relevant robot developers face when applying standards concerning rehabilitation, personal care, and agricultural robots. In particular, the webinar will focus on identifying challenges roboticists (including developers, policymakers, or ethicists) found in ISO

[4] *See* here for the workshop presentation.
[5] *See* here for the workshop presentation.
[6] *See* here for the workshop presentation.

13482:2014 on personal care robots, IEC 80601–2–78–2019 on rehabilitation robots, and ISO 18497:2018 on agricultural machinery and tractors. The goal is to know how to build an information link between different communities to create norms that frame robot development in key sectors adequately.[7] Moreover, both sessions were geared towards obtaining a better insight into the usefulness of LIAISON based on the wider stakeholder community. Moreover, to ensure maximum community participation in the individual ERF workshop by LIAISON, the COVR Project was involved in promoting this event.

The European Robotics Forum

The ERF is the most influential meeting of the robotics community in Europe, organised annually by euRobotics under SPARC, the Public-Private partnership for Robotics in Europe. After its start in San Sebastian in 2010, the European Robotics Forum has grown into a major annual event with hundreds of attendees every year. The ERF2021 covers all aspects and current themes related to the field of robotics. It welcomes a wide range of stakeholder groups (including researchers, engineers, managers, and a growing number of entrepreneurs, business people, and public funding officers from all over Europe) to discuss technology push and market pull and how innovation in robotics and robotics-related AI can be accelerated.

3.1.4. ENGAGEMENT WITH SEVERAL COMMUNITIES

To map the existing gaps and inconsistencies in current robot regulatory frameworks and gain insight into the potential and usefulness of LIAISON, we have extensively engaged with the European Digital Innovation Hubs in the domains of healthcare and Agriculture, namely DIH-HERO and DIH-AgROBOfood. More specifically, within these Digital Innovation Hubs, we have engaged with involved researchers and work package leaders on standardization and ethics. Moreover, we have established collaboration between LIAISON and both Digital Innovation Hubs to engage their respective communities in the LIAISON activities. This included their active support in the distribution and refinement of the above feedback surveys, a collaborative workshop at the ERF, and possibilities for further joint domain-specific webinars at a later date, domain-specific discussion on identified issues in current robot regulatory frameworks (e.g., CEMA industry expert discussion on ISO 18497:2018). Likewise, we have further expanded on the partnership with the COVR Project for the same purposes.

Finally, we actively engaged with relevant stakeholders in our networks (including robot developers, policymakers, and academia) to expand the reach of LIAISON. Examples include PAL Robotics, the Robotics4EU Project - which aims to increase awareness about ethics, legal, socio-economic, cybersecurity, data protection and further non-technological aspects of robotics -, Agreenculture - a French company that designs, develops and produces autonomous solutions for the agricultural world -, the European Agricultural Machinery Association (CEMA), EC representatives, academia, and the wider community present at the above ERF workshops.

[7] For an overview of the workshop program, see table 2 (annex).

3.1.5. POLICY AND STANDARD MAKING INSTITUTIONAL MEETINGS

To prove the feasibility and added value of the creation of this link between robot developers and relevant regulators, for the purposes of 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). As part of LIAISON, three formal meetings were held with relevant policy and standard makers at an early stage of the project to explore how LIAISON is perceived by them and how they can contribute to LIAISON in helping relevant policy and standard makers frame robot development adequately. The policy and standard makers involved for this purpose represent both private standardisation organisations and the European Commission.[8]

3.2. PREPARATION & TIMELINE

With regard to the above methods, below an overview if provided of the related preparation and timeline:

OVERVIEW PREPARATION & TIMELINE		
ACTIVITY	**TIMELINE**	**PREPARATION**
Desktop research	Jan-April 2021	For this report, we conducted a desktop and literature review and compiled sources for four months, spanning from January to April 2020. These sources include research articles, web pages, and product catalogs, retrieved from online academic databases and web search results on Google and Google Scholar.
Surveys	March-April 2021	The feedback surveys on existing inconsistencies, confusing categories, and uncovered challenges in ISO 13482:2014 (on personal care robots), IEC 80601-2-78:2019 (on rehabilitation robotics), and ISO 18497:2018 (agricultural machinery and tractors) is powered by Qualtrics and consists of three individual assessment sections: 1) General; 2) specific topics; and 3) additional feedback.
Workshop(s)	March-April 2021	The above workshops took place virtually and included a Google Slide presentation on LIAISON in line with the surveys that match feedback loops 1 and 2. Moreover, the ERF workshops included an interactive element powered by the Mentimeter polling software.
Community engagement	Jan-April 2021	Community engagement covered a range of formats, including telco meetings, additional events, and emails. Persons of interest were retrieved from our existing networks and through events that we attended or obtained by reference.

[8] Personal names are anonymised for the purpose of this report.

Policy and standard making institutional meetings	January-March 2021	To conduct exploratory meetings with relevant standard makers, we employed the format of two online exploratory meetings during which we discussed the feasibility, usefulness, and acceptability of LIAISON as a means to align robot and regulatory development and improve robot safety standards and legal frameworks from the perspective of the relevant standard makers. For a further overview of the meeting agenda, see tables 3 and 4 in the annex. The meetings covered a range of topics in line with those presented in the feedback surveys matching feedback loops 1 and 2, and the meetings took place through the Virtual Conferencing platform Microsoft Teams.

3.3. DATA CAPTION

The data obtained through the above means was collected, stored, and analyzed according to their format. Data retrieved through the LIAISON surveys and the accompanying data obtained through the interactive ERF workshops has been stored in our storage. During the research, this project uses the safe storage of the University ICT department (ISSC) network to keep all the generated data. At Leiden University, each scientist has a personal folder with exclusive access where to organize projects named ‘university personal network storage (p:).’ This project will use p:, and it will be managed by the IT Services of Leiden University. A backup is made regularly. Access is limited to the researchers involved in the project. Upon termination of the project, the researchers will store all data on the university server for a limited period.

The feedback obtained through community engagement and exploratory meetings has been captured and stored in various separate formats, including meeting minutes, additional project notes, and email threads. The results of the analysis of these data and the findings from desktop research are presented in the following section.

4. EU LEGISLATION & SAFETY STANDARDS

4.1. PUBLIC VS PRIVATE POLICY MAKING

4.1.1. PUBLIC POLICY MAKING

Public policymaking can be generally defined as a system of laws, regulatory measures, courses of action, and funding priorities concerning a given topic promulgated by a governmental entity or its representatives. Examples of public policy making activities within the field of new technologies, among which robots, can be found at the European level. This has resulted in a wide variety of EU-wide measures, among which in particular Directives and Regulations. Important to note within this context is that according to article 288 of the Treaty on the Functioning of the European Union (TFEU), 'a directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods,' and 'a regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.'

Examples of such measures can be found in the domain of products (e.g., the Directive on general product safety and the Directive on Liability for Defective Products), personal data (e.g., the General Data Protection Regulation (GDPR)), the context of use (the Machinery Directive, the Regulation on Medical Devices, the Directive on the safety on toys), and concerning specific technology-related parts (the Low Voltage Directive, the Electromagnetic Compatibility Directive, and the Radio Equipment Directive). The EU and governments worldwide are thus undertaking many-many measures to frame robot and AI technology development.

Fueled by the end-results of many EU Projects (here only acronyms: ROBOLAW, INBOTS, NoBIAS, CARAMEL, XAI, EIW3R, SHERPA, Humane AI, VIRT-EU, SIENNA), these regulatory efforts represent a significant step towards regulating a not yet very well-known technological development. However, the EU struggles to release technology-savvy, sector-specific guidelines (Fosch-Villaronga, 2019). Some official reports contain references to science fiction (EurParl, 2017). While the recent publication of the new draft AI Regulation by the European Commission and the general presentation by the EC of the EU's approach to AI - which centers on excellence and trust - seems to be promising in this sense, it is still to be seen what the practical effectiveness of this new framework will be. Another specific concern that has been raised within this context is whether these regulations can, in practice, cope with tech development? What we have found with new technologies is that public policymaking is often outdated and tech-neutral. Moreover, legal responsiveness does not always follow technological development timely or at all as a consequent step (Collingridge, 1980; Marchant, 2011; Newlands et al., 2020).

4.1.2. PRIVATE POLICY MAKING

As a result of the inability of regulators to keep up with the fast pace of innovation and propose regulatory actions matching state of the art and the foreseeable impacts such emerging technologies may have, many-many private actors (e.g., ISO, BSI, IEEE) have developed private standards aiming to mitigate the ethical and legal risks and concerns

posed by robotics. A standard is a document that provides requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose. Standards and their development frame, guide, and normalize almost all areas of our lives. Standards allow technology to work seamlessly and establish trust so that markets can operate smoothly. They a) provide a common language to measure and evaluate performance; b) make interoperability of components made by different companies possible; and c) protect consumers by ensuring safety, durability, and market equity.

While these soft-law instruments are excellent for reaching international agreements on relevant topics, such private policy instruments have also raised practical concerns, namely: a) Standardisation involves a multiplicity of actors (e.g., ISO, BSI, and IEEE); b) standardization shifts the centralization of regulation from public democratic processes to private ones that do not have the guarantees of the rule of law; c) standards in itself are not binding (if not harmonized or included in contractual clauses); 4) standards don't fix consequences for violations or noncompliance; 5) standards are usually mono-impact, focus on one aspect (e.g., on safety, often leading to a multiplicity of standards for one particular domain; and 6) standards often include confusing categories.

4.2. HARMONISATION

Within the context of the above, it is important to note the role of harmonization within the landscape of public and private policymaking. A harmonized standard is a European standard elaborated based on a request from the European Commission to a recognized European Standards Organisation to develop a European standard that provides solutions for compliance with a legal provision under EU law. This results in the drafting of guidelines that the requested standards must respect to meet the essential requirements or other relevant EU harmonization legislation provisions. Important to note within this context is that the applicable standard thereby becomes binding and that compliance with harmonized standards provides a presumption of conformity with the corresponding requirements of harmonization legislation.

Due to the judgment of the European Court of Justice (ECJ) in the James Elliot case in October 2016 (C-613/14), which classifies harmonized standards as "part of Union law," the Commission has most recently felt compelled to substantially modify the standardization procedure, which makes efficient standardization more difficult. This led the German Federal Ministry for Economic Affairs and Energy ("BMWi") to commission a legal opinion on specific questions regarding the consequences of the ECJ judgment and the new procedural rules of the Commission introduced on the occasion of the judgment.[9] According to the BMWi, the decision of the ECJ in the case of James Elliott, in which the Court concludes that harmonized standards form "part of Union law", relates solely to the specific context of the Court's jurisdiction in preliminary rulings under Article 267 TFEU. The BMWi indicated that it is evident that the Court did not intend to thereby subject harmonized standards to the same conditions of validity and the same legal consequences that apply to all other EU law, and

[9] *See* here for Legal Opinion on the European System of Harmonised Standards commissioned by the German Federal Ministry for Economic Affairs and Energy ("BMWi").

thus ultimately call into question the New Approach.[10] The latter is based on the fact that, beyond legislative processes, the essential requirements of harmonization legislation are specified by harmonized standards of the private standardization organizations, the application of which is voluntary.

4.3. OUR FOCUS

For this report, we focus on private policy-making activities. In particular, we focus on three specific safety standards that have spanked much discussion within their respective communities within the context of technological, in particular, robot - development: 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). Where relevant, we complement our legal analysis of these policy documents with the results from ongoing public policy-making activities at an EU level.

[10] *See* OJ 1985, no. C 136, p. 1.

5.REGULATORY INCONSISTENCIES & CHALLENGES

5.1. INTRODUCTION

A coordinated relationship between technology and regulation developments may result in disconnections between both when new technological concepts are pursued or when developers experiment with new designs, implementation, and usages (Fosch-Villaronga & Heldeweg, 2018). As noted above, new applications may not fit into existing (robot) categories, legislation (private and public policy making) might be outdated and with confusing types, and technology-neutral regulations may be hard to follow for developers who are concerned about their particular case. Moreover, machine learning techniques will increasingly pose questions about ensuring safety when there is a substantial modification of the device. These factors altogether hinder the identification and the addressing of the ELS issues associated with the use and development of technology by governments and public regulatory bodies, who struggle to catch up with technology (r)evolution (Fosch-Villaronga & Golia, 2019).

This section maps the existing inconsistencies and challenges experienced in 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).

5.2. SAFETY STANDARDS UNCOVERED CHALLENGES

The evaluation of these standards through the above methods has led us to come to the main findings as illustrated in the table below. These findings have been obtained through the methods described in section 3.1. As the surveys and interactive sessions at the relevant ERF workshops were built upon the same sets of questions, we combined both to provide a representative and complete overview of stakeholder responses. Where further elaboration is provided, the results obtained through the other methods are also integrated.

Since we were using different interactive tools (surveys in qualtrics and mentimeter), some questions had more respondents than others. This makes it a bit difficult to say, in total, how many respondents participated. Still, we have indicated these numbers in more detail for each of the questions and statements here below, where relevant.

5.2.1 ISO 13482:2014 | REGULATORY INCONSISTENCIES & CHALLENGES

SAFETY STANDARDS UNCOVERED CHALLENGES
ISO 13482:2014 | REGULATORY INCONSISTENCIES & CHALLENGES
Scope of application
ISO 13482:2014 has been developed to recognize the particular hazards presented by newly emerging robots and robotic devices for new applications in non-industrial environments for providing services rather than manufacturing applications in industrial applications. As such, ISO 13482:2014 focuses on the safety requirements for personal care robots in non-medical applications. More specifically, the standard specifies

requirements and guidelines for the inherently safe design, protective measures, and information for the use of personal care robots (...), in particular, the following three types of personal care robots', namely: 1) mobile servant robots; 2) physical assistant robots, and 3) person carrier robots. According to this standard, a personal care robot should be defined as *'a service robot that performs actions contributing directly towards the improvement in the quality of life of humans, excluding medical applications'*.

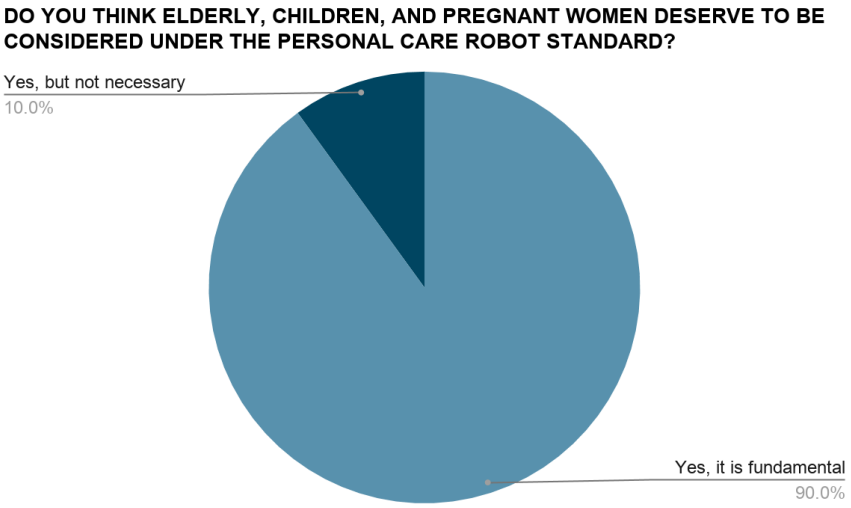
This standard describes hazards associated with the use of these robots in human-robot physical contact applications and provides requirements to eliminate or reduce the risks associated with these hazards to an acceptable level. As such, the standard covers a total of 6 sections, namely: 1) scope; 2) terms and definitions; 3) safety requirements & protective measures; 4) safety-related control system requirements; 5) verification and validation; 6) information for use, and 7) annex.

Concerning experienced challenges and inconsistencies, the responses to the LIAISON survey on ISO 13482:2014, while based on a very limited number of responses, point out that robot developers are either neutral or only slightly satisfied concerning ISO 13482:2014 and experience its implementation as doable. The respondents have varying experiences with the standard and highlight that the standard could benefit from their guidance, is easy to follow and useful as it is, and that while useful, the standard could use different and more concrete examples to be easier to understand. Moreover, while the respondents indicate that the standard is either moderately clear or very clear with regard to its language and lay-out, they nevertheless see room for improvement in the following sections: Safety requirements & protective measures, Safety-related control system requirements, and Verification and validation. Interestingly, 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 indicated that the TC299 sees potential areas for improvement of the standard in its scope and structure. In addition, regarding the substantial provisions of the standard, the respondents to the surveys have identified room for improvement in the following sections: Safety-related control system requirements, Verification and validation, and Annex.

Below, we highlight some of the specific challenges and inconsistencies experienced in ISO 13482:2014 as obtained through the methods described above.

CHALLENGE/ INCONSISTENCY	*DESCRIPTION*
Blurred scope and unclear definitions	ISO 13482:2014 does not define Personal care, but it excludes medical applications. This completely blurs the scope of the standard. As noted earlier, legislation (private and public policy making) might be outdated and with confusing types. An example of this can be found in ISO 13482:2014, which defines the term *personal care robot*, but does not further elaborate on the meaning of personal care while still excluding medical applications from its scope. 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. However, their domain is also on the border with medical robots.

	Moreover, during the ERF workshops, public responses 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). One of the most notorious confusing categories when it comes to the domain of 'healthcare' is whether a device 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. For the standards, this ended up in two standards/categories: those for medical use and well-being. However, the medical device regulation 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. This 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 ISO 13482:2014 will provide any room for those robotic devices that flirt the boundary of medical and non-medical. In this regard, it stated that the revised version of the standard would cover service robots, thereby moving away from the focus on personal care robots.

Lacking attention for specific vulnerable user groups	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, with no other information, this statement conveyed the impression that the standard was a temporary benchmark and that there should be special requirements for different users. This brings about uncertainties concerning the protected scope of the framework. Nevertheless, the revised standard shows no changes in this respect (Fosch-Villaronga, 2019). Moreover, 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.  **Fig. 3.** Do you think the elderly, children, and pregnant women deserve to be considered under the personal care robot standard (10 respondents)? More specifically, within this context, participants indicated that concrete aspects which should be taken into account for these different users include 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. The relevant participant said that concerning the former only force and pressure threshold for contacts should be considered. At the same time, it is essential to note that revision activities are still debating and regarding this issue. Moreover, within the context of this debate, the importance of adequate training was also stressed, thereby highlighting the need for a reconsideration of the provided training.
The standard does not address exoskeletons	ISO 13482:2014 requires improvements in terms of safety requirements and protective measures for exoskeletons.

adequately	For instance, while the balance is the second cause of falls in the elderly, travel instability measures are not applicable to physical assistant robots. Indicators about different subjects' ability to maintain balance suggest improving the ISO 13482:2014 to address collision instability specifically. Information about stability in unstructured environments could indicate validating measures to address the risk of falls (Fosch-Villaronga, 2019). Another example is that, while obstacles can pose a risk to normal gait (e.g., stairs, objects), the standard, however, states that collisions with safety-related objects, other robots, fragile safety-related objects, walls, permanent/unmovable barriers "are not applicable to restraint-type physical assistant robots." Even though years later a technical report was released, specific hazards may be neglected because "at the time of publication, the test methods (...) have not been implemented or evaluated broadly" (ISO/TR 23482-1:2020 Application of ISO 13482:2014 safety-related test methods). In this sense, ISO/TR 23482-1:2020 suggests "users of this document are therefore advised to apply the tests with care." Moreover, ISO 13482:2014 does not include Fear of Falling (FoF) as a potential hazard, and different subjects' safety requirements remain undetermined. The methods for verifying and validating exoskeletons' safety concerning mental stress do not include practical tests, and there is a lack of research on the correlation between FoF and safety. Moreover, there is a lack of agreement on testing and validating risks of falling, and FoF could be a suitable indicator for reaching agreed test methods. Contrasting values of stress, perceptibility, acceptability, functionality, usability, and Falls Efficacy Scale (FES)) may indicate a correlation between the FoF and safety, and propose a revision of the ISO 13482:2014 to include (i) FOF as a specific hazard, (ii) with specific measures for different categories of subjects, and (iii) demand practical tests among the verification and validation methods for mental stress-related safety measures. Since ISO 13482:2014 admits the need for data on different categories of people, the Performance Indicators (PIs) could recommend the standardization of safety measures that distinguish between people of different ages and genders.
Accounting for intrinsic factors	Intangible and intrinsic factors to the user, such as the user's safety perception or user control, can also constrain the performance of the relevant personal care robot. Roboticists should implement additional safeguards for different types of users. Lack of user experience can significantly impact self-confidence, and thus, it may impact the correct performance of the device. Nevertheless, ISO 13482:2014 does not take this into account.
Accounting for autonomous decisions	While ISO 13482:2014 takes into account the consequences of an error in the autonomous decisions of the robot, 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 clarify what the criteria are to decide on this. Silence on these matters, however, does not provide a respectable safeguard baseline. Moreover, 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 whether a broader range of factors should be taken into account in the standard in this regard. For instance, it is not certain 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 GDPR. While the GDPR seems to have been drafted with computer systems in mind, cyber-physical systems have been largely disregarded (Felzmann et al., 2018).
Lacking attention for intangible aspects	The need to establish relationships and lasting attachments between humans and social robots. Robots require a constitution that is more real and alive than mere machines. The resulting imperfect and unique robot personality may compromise the robot’s behavior. In turn, not obeying the relevant regulations may challenge the safety of those therapies that rely upon such predictability to work with users with special needs (Fosch-Villaronga, 2019). Since there are no guidelines on using social communication with the user, and no guidelines on how companionship works, it is not clear whether the users are safe. For instance, regardless of potential physical harm, the data protection rights of the user may be violated as well. Where a relationship of trust has been established between the robot and its user, the user may be inclined to share personal information with the robot without realizing 1) the robot is not a person, and 2) there might be a party collecting and processing this information. This is particularly troublesome where the user cannot understand and adequately assess the implications this may have (Fosch-Villaronga, 2019). This is particularly important, seeing as respect for the physical and psychical integrity of the person are fundamental rights under the European Charter of Fundamental Rights. In line with this, the European Parliament speaks of physical and psychical human dignity, thereby stating that users should have the right to use a robot without risk or fear of physical or mental harm. However, as of yet, no standard regulates psychological safety.

5.2.2 ISO 80601-2-78 | REGULATORY INCONSISTENCIES & CHALLENGES

SAFETY STANDARDS UNCOVERED CHALLENGES
**ISO 80601-2-78	REGULATORY INCONSISTENCIES & CHALLENGES**
Scope of application
IEC 80601-2-78:2019 ‘applies to the general requirements for basic safety and essential performance of medical robots that physically interact with a patient with an impairment to

support or perform rehabilitation, assessment, compensation, or alleviation related to the patient's movement functions, as intended by the manufacturer.' In this context, *Rehabilitation, assessment, compensation, and alleviation robot* means a 'Medical robot intended by its manufacturers to perform rehabilitation, assessment, compensation or alleviation comprising an actuated applied part.' As such, the standard covers a total of 15 general sections, namely: 1) scope, object, and related standards; 2) terms and definitions; 3) general requirements; 4) classification ME Equipments and ME Systems; 5) identification, making and documents ME Equipment; 6) protective measures and accuracy; 7) hazardous situations and fault conditions ME Equipment; 8) programmable electrical medical systems; 9) construction of ME Equipment; 10) ME Systems; 11) electromagnetic compatibility of ME equipment and ME Systems; 12) requirements and tests electromagnetic disturbances; 13) usability; 14) Requirements ME Equipment and ME Systems, and 15) Annex. This standard builds upon the more general standard IEC 60601-1:2005, and can only be read/understood in combination with this more general standard.

Concerning experienced challenges and inconsistencies, the responses to the LIAISON survey on IEC 80601-2-78:2019, while based on the very limited number of four responses, point out that robot developers are either neutral or only slightly satisfied about IEC 80601-2-78:2019, and hold widely differing opinions concerning their satisfaction with the implementation of the standard, namely: neither difficult nor easy, very difficult, and doable. The respondents have varying experiences with the standard. They highlight that the standard is easy to follow and useful as it is, that the standard could benefit from the guidance of robot developers, that the standard requires a general revision to be valuable and easy to follow, that while useful, the standard could use additional and more concrete examples to be easy to understand. They also believe that the standard requires further and more concrete examples to be helpful and easy to follow, that while easy to understand, the standard requires a general review to be useful. Moreover, the respondents identify that the language used in the standard is moderately clear, very unclear, and very clear, clearly indicating contradictory experiences. They also believe that the standard layout is clear, moderately clear, and slightly unclear. More specifically, with regard to language use they see room for improvement in the following sections: Scope, object and related standards, General requirements, Classification ME Equipments and ME Systems, Protective measures and accuracy, Hazardous situations and fault conditions ME Equipment, Programmable electrical medical systems, Construction of ME Equipment, ME Systems, Electromagnetic compatibility of ME Equipments and ME Systems, Requirements and tests electromagnetic disturbances, Usability, and Requirements ME Equipment and ME Systems; and room for layout improvement in the following sections: Scope, object and related standards, Terms and definitions, General requirements, Classification ME Equipments and Systems, Identification, making and documents ME Equipment, Protective measures and accuracy, Hazardous situations and fault conditions ME Equipment, Programmable electrical medical systems, Construction of ME Equipment, ME Systems, Electromagnetic compatibility of ME Equipments and ME Systems, Requirements and tests electromagnetic disturbances, Usability, Requirements ME Equipment and ME Systems, and Annex.

Below, we highlight some of the specific challenges and inconsistencies experienced in IEC 80601-2-78:2019 as obtained through the methods described above.

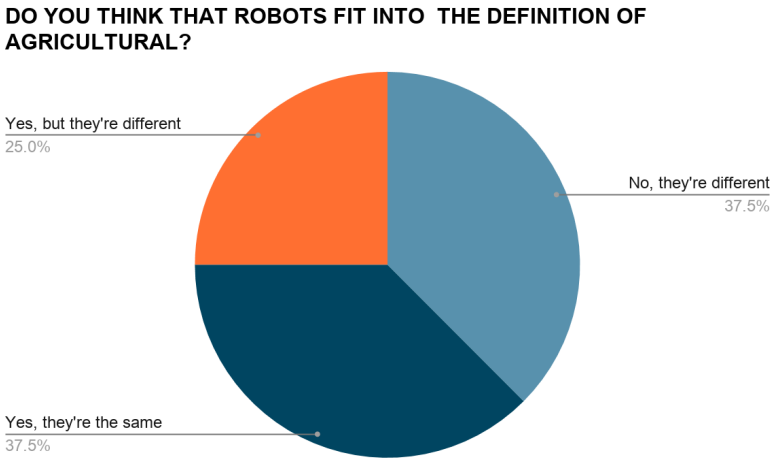
CHALLENGE/ INCONSISTENCY	*DESCRIPTION*
Relevant	Before rehabilitation robots can be made commercially available in

information is scattered across multiple standards and regulations	the EU, the manufacturer needs to demonstrate that the device is safe. However, the safety validation of rehabilitation robots is complex. This is partly because the field of rehabilitation robots is relatively new, which reduces the availability of best practices and applicable safety standards. 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. Moreover, manufacturers of rehabilitation robots should be aware that article 1.6 of the Medical Device Regulation (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 has to 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 is in agreement with the EU legislation. However, for medical devices, the current applicable harmonized standards are harmonized for the MDD. This means that for the period 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 Medical Device Regulation (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.
Lacking validation measures	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., 2018) 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 - step-by-step guides on how to validate the safety of your system - 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.

5.2.3 ISO 18497:2018 | REGULATORY INCONSISTENCIES & CHALLENGES

SAFETY STANDARDS UNCOVERED CHALLENGES

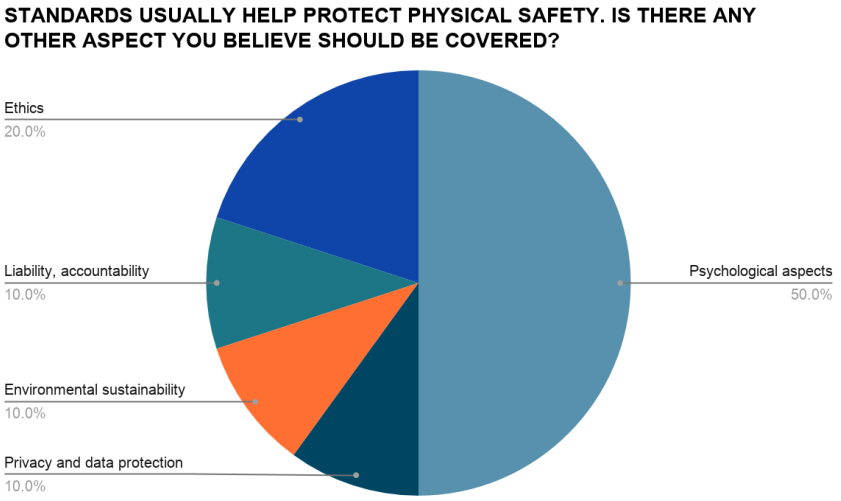
ISO 18497:2018 | REGULATORY INCONSISTENCIES & CHALLENGES	
Scope of application	
ISO 18497:2018 specifies principles for the design of highly automated aspects of highly automated machines and vehicles (...) during agricultural field operations. In addition, it provides guidance on the type of information on safe working practices to be provided by the manufacturer. Within this context, a *highly automated agricultural machine* should be understood as a 'mobile vehicle or machine with or without on-board operator allowing highly automated operation'. The purpose of this document is to assist in the provision of safety requirements, means of verification and information for use to ensure an appropriate level of safety for agricultural and forestry tractors and self-propelled machines with functions allowing highly automated operations. More specifically, this standard deals with all the significant hazards, hazardous situations and events, relevant to agricultural and forestry tractors and self-propelled machines allowing highly automated field operations when used as intended and under the conditions of misuse foreseeable by the manufacturer during normal operation and service. As such, the standard covers a total of 6 sections, namely: 1) scope; 2) terms and definitions; 3) safety requirements & protective or risk reduction measures; 4) verification and validation of the safety requirements and protective or risk reduction measures; 5) information for use; 6) annex With regard to experienced challenges and inconsistencies, the responses to the LIAISON survey on ISO 18497:2018, while based on a very limited number of responses, point out that robot developers hold widely differing opinions with regard to their satisfaction with the standard, namely: neither satisfied nor dissatisfied, slightly satisfied, and very unsatisfied. The same applies to their experience with the implementation of the standard, namely: neither difficult nor easy, doable, and very difficult. The respondents have varying experiences with the standard and highlight that the standard requires a general revision to be useful and easy to follow, and that while useful, the standard could use additional and more concrete examples to be easy to understand. Moreover, the respondents identify that the language used in the standard is very clear, moderately clear, and slightly unclear - clearly indicating contradictory experiences -, and that the standard lay-out too is very clear, moderately clear, and slightly unclear. More specifically, with regard to language use they see room for improvement in the following sections: Scope, Terms and definitions, Safety requirements & protective or risk reduction measures, Verification and validation of the safety requirements and protective or risk reduction measures, Information for use, and Annex; and room for lay-out improvement in the following sections: Scope, Terms and definitions, Safety requirements & protective or risk reduction measures, Verification and validation of the safety requirements and protective or risk reduction measures, and Information for use. In addition, regarding the substantial provisions of the standard, the respondents have identified room for improvement in the following sections: Scope, Terms and definitions, Safety requirements & protective or risk reduction measures, Verification and validation of the safety requirements and protective or risk reduction measures, and Information for use. Below, we highlight some of the specific challenges and inconsistencies experienced in ISO 18497:2018 as obtained through the methods described above.	
CHALLENGE/ INCONSISTENCY	*DESCRIPTION*
Unclear definition and scope	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? Also, among the 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, others thinking that they do not.  **Fig. 4.** Do you think that robots fit into the definition of agriculture machinery (8 respondents)? Moreover, engagement with DIH-AgROBOfood's standards work package leader has led to the finding that no safety standard addresses agricultural robots during a rapidly advancing field yet. More specifically, during a meeting with CEMA it was indicated that there is not much focus on the concept of safety within agricultural machinery and robotics due to the novelty of the field. This may nevertheless become a more important topic over time. 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 in the (near) future.
New functionalities, new applications, and new risks	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. Operators are not always present with the robot but are legally responsible for the safety of operations and must be able to place the machine in safe mode at all times.
Compliance in an ill-suited and inaccurate framework	With risk analysis and the performance of tests and adjustments in the design phase, the key is to develop reliable, safe machines within a regulatory context that is at times 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.
Lacking detail	There are no requirements in ISO 18497:2018 and others norms applicable to detection systems in terms of climatic conditions. Measuring and characterizing harsh climatic conditions is very challenging. 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.

5.2.4 CROSS-DOMAIN | REGULATORY INCONSISTENCIES & CHALLENGES

SAFETY STANDARDS UNCOVERED CHALLENGES	
GENERAL | REGULATORY INCONSISTENCIES & CHALLENGES	
CHALLENGE/ INCONSISTENCY	*DESCRIPTION*
Revision time	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 domains, 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 be able 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.
Standards should shift from mono-impact to multi-impact approach	While the standard is concerned with physical safety requirements, however, 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. This highlights that the standard may not be offering enough protection to users. 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 (see D1.2) multi-stakeholder approach.  **Fig. 5.** Standards usually help protect physical safety. Is there any other aspect you believe should be covered? (10 respondents)? Moreover, 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. As such, it is clear that robots, to be safe, need to comply with the safety requirements set by private standards and the law to ensure that the rights and protection of the user are not compromised.
The cross-domain nature of robotics raises a dilemma for roboticists	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).
The concept of safety focuses too much on physical safety	Robots and artificial intelligence (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 the integration of 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 conceptualised rather narrowly (Fosch-Villaronga & Mahle, 2021). Thus, to address safety comprehensively, AI demands a broader understanding of safety, extending beyond physical interaction, but covering aspects such as cybersecurity, and mental health. Moreover, the expanding use of machine learning techniques will more frequently demand evolving safety mechanisms to safeguard the substantial modifications taking place 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, cyber security, temporal, and societal need to be considered for robot development. 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 truly safe to use.
The autonomy levels are not defined for robots, only for self-driving cars.	The *levels of automation* 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." (ISO 8373:2012). For the automotive industry, the Society of Automotive Engineers established automation levels to clarify the progressive development of automotive technology that would, at some point, remove the human from the driving equation (SAE International). However, no universal standards have been defined for progressive autonomy levels for medical robots. Yang et al. 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 (Yang et al., 2017)). The effort is a significant step towards bringing more clarity to the field, but the model needs more detailing on how it applies to specific types of medical robots. Medical robots' embodiment and capabilities differ vastly across surgical, physically/socially assistive, or serviceable contexts and the involved human-robot interaction is also very distinctive. Socially assistive robots interact with users socially, performing a task for the user, but there is close to zero-contact with the user; physically assistive robots (e.g.,

	lower-limb exoskeletons), on the contrary, work towards a seamless integration with the physical user's movement; and surgical robots are collaborative robots that extend the surgeon's abilities.

6. CONCLUSIONS

Robot manufacturers deal with many different legal frameworks, including standards and regulations. This state of affairs increases legal uncertainty, as it is unclear what regulations developers have to follow to comply with the legal system, increasing legal uncertainty.While compliance tools like the H2020 COVR Toolkit can help in this respect, the platform leaves room for desire: especially for new robot manufacturers, a clarification of the applicable legal framework would help in reducing the complexity in robot legal compliance. This study brought into view the inconsistencies, dissonances, and inaccuracies of existing frameworks with respect to robot technologies. In particular, LIAISON focused on personal care robots (ISO 13482:2014), rehabilitation robots (IEC 80601–2–78–2019), and agricultural robots (ISO 18497:2018).

The findings in this report generally indicate that while standardisation activities have shown great effort into creating a safety framework for the relevant robots, they require careful evaluation, review and multi-stakeholder collaboration to offer optimal protective framework for user protection. These findings can be summarised as follows:

<table>
<tr><th colspan="3">SUMMARY | INCONSISTENCIES & CHALLENGES SAFETY STANDARDS</th></tr>
<tr><td>ISO 13482:2014</td><td>ISO 80601-2-78</td><td>ISO 18497:2018</td></tr>
<tr><td>Blurred scope and unclear definitions</td><td rowspan="2">Relevant information is scattered across multiple standards and regulations</td><td>Unclear definition and scope</td></tr>
<tr><td>Lacking attention for specific vulnerable user groups</td><td>New functionalities, new applications, and new risks</td></tr>
<tr><td>The standard does not adequately address exoskeletons</td><td rowspan="4">Lacking validation measures</td><td>Compliance in an ill-suited and inaccurate framework</td></tr>
<tr><td>Accounting for intrinsic factors</td><td rowspan="3">Lacking detail</td></tr>
<tr><td>Accounting for autonomous decisions</td></tr>
<tr><td>Lacking attention for intangible aspects</td></tr>
<tr><td colspan="3">GENERAL</td></tr>
<tr><td colspan="3">Revision time</td></tr>
<tr><td colspan="3">The standard should shift from mono-impact to multi-impact</td></tr>
<tr><td colspan="3">The cross-domain nature of robotics raises a dilemma for roboticists</td></tr>
<tr><td colspan="3">Automation levels for robot technologies need to be defined</td></tr>
<tr><td colspan="3">The concept of safety requires revision</td></tr>
</table>

LIAISON aims to contribute in this regard by mapping legal inconsistencies and challenges in the relevant standards with the help of relevant stakeholders, and liaising robot development with policymaking by channeling these findings to the relevant policymakers.

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9. ANNEX

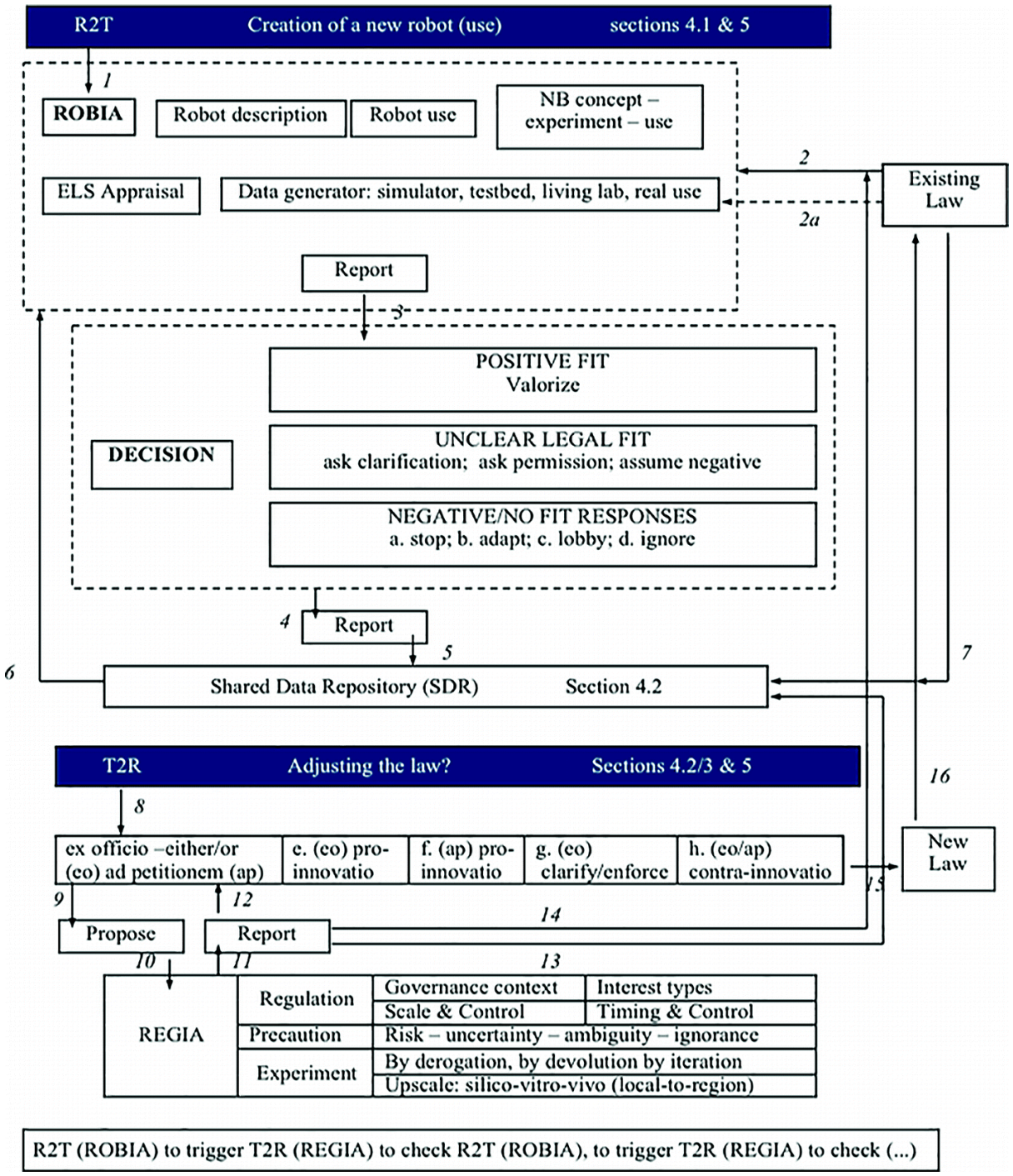

Figure 1: Preliminary iterative process for robot governance[11]

[11] 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

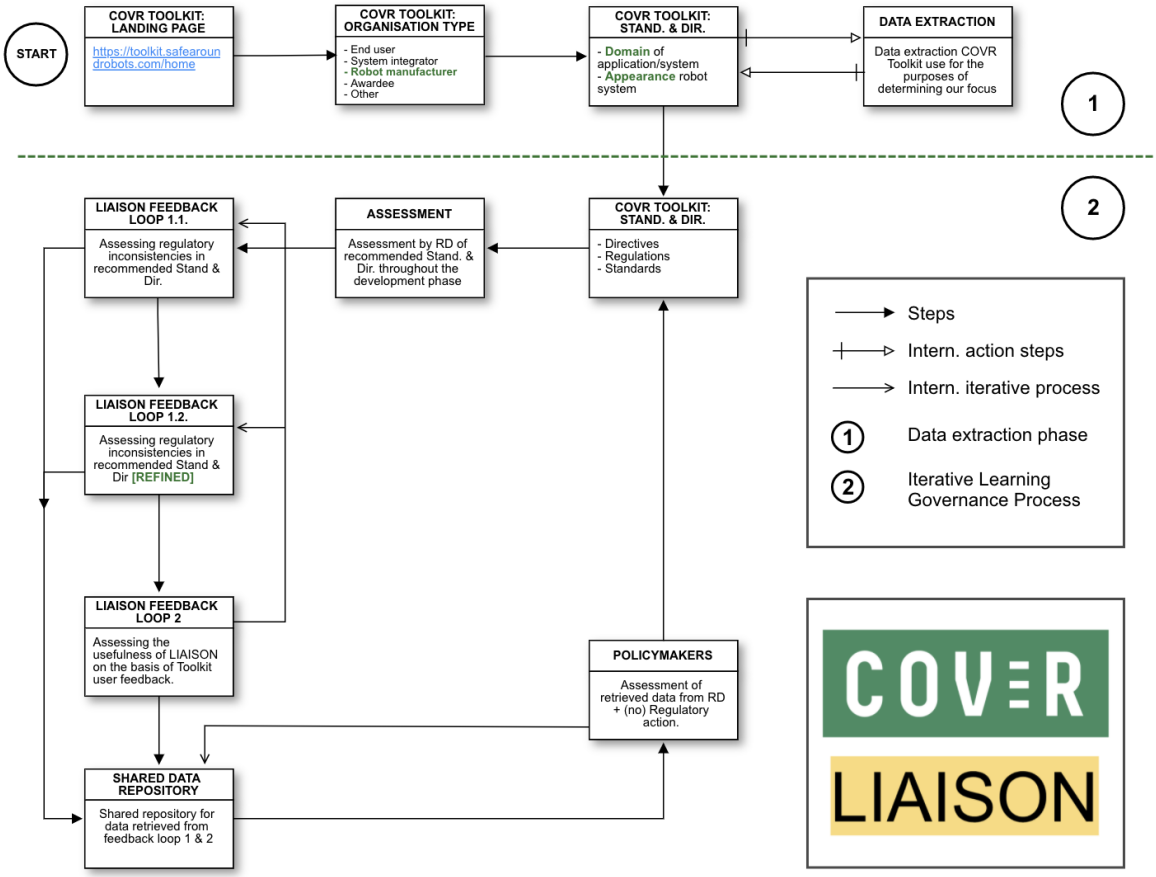

Figure 2: LIAISON Research Project mechanism

EC WORKSHOP PROGRAM		
TIME	**WHO**	**WHAT**
09:00 – 09:10	IDATE	Short welcome, presenting the agenda
09:10 – 09:20	EC	Short presentation on the study by EC (e.g. relevance, vision)
09:20 – 09:30	LIAISON	Introductory presentation on LIAISON: Liaising robot development and policy making
09:30 – 09:55	IDATE / FOKUS	Presentation on preliminary outcomes of the study : Feedback on going relevant standardisation efforts for safety standards and concerns/developments around robotics use cases in medical industry

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.)

		Focus on surgical robots, telepresence in healthcare and rehabilitation skeletons
09:55-10:00	**BREAK**	
10:00 – 11:30	ALL	Discussion on use cases, related safety standards, potential gaps Roundtable format including participants (tbc) from EC, ISO, CENELEC, IEEE, academics and from medical robotics providers/labs (Hocoma, Bristol Robotics Lab, PAL Robotics
11:30 – 12:00	IDATE	Summary of discussion, definition of next steps, closing of workshop

Table 1: Program European Commission workshops "Trends and Developments in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots"

PROGRAM ERF WORKSHOP LIAISON	
TIME	**TOPIC**
15h40-15h45	Welcome & Introduction
15h45-16h	**LIAISON** Aims and goals of the H2020 COVR Award
16h-16h20	**Standards, robots, and developers** General interactive session
16h20- 16h40	**Personal care, rehabilitation, and agricultural robots** Specific interactive session
16h40-16h55	**Discussion**
16h55-17h	**Wrap-up**

Table 2: Program ERF Workshop LIAISON: Liaising robot development and policy making

MEETING AGENDA	
TOPIC	**TIME**
Personal introductions	**+/- 5 mins**
Presentation LIAISON Research Project	**+/- 10 mins**
Explanation LIAISON mechanism	**+/- 5 mins**

Usefulness & feasibility LIAISON	**Initial thoughts on usefulness and feasibility LIAISON**	**+/- 15 mins**
	Standard making, inconsistencies and current approach in standard making	
	Opportunities and potential pitfalls LIAISON	
Exploring synergies	**How can LIAISON be of help?**	**+/- 15 mins**
	How can policy/standard makers be of help?	
	Views on long-term cooperation and feasibility	
Moving forward + wrap-up	**Next steps LIAISON**	**+/- 15 mins**
	Action-points meeting	
	Follow-up	

Table 3: Meeting agenda exploratory meetings 1 and 2 with representatives of private standardisation organisations.

MEETING AGENDA		
TOPIC		**TIME**
Personal introductions		**+/- 5 mins**
Presentation LIAISON Research Project		**+/- 10 mins**
Explanation LIAISON mechanism		**+/- 5 mins**
Usefulness & feasibility LIAISON	**Initial thoughts on usefulness and feasibility LIAISON**	**+/- 15 mins**
	EU legislation and safety standards uncovered challenges & harmonisation gap	
	Opportunities and potential pitfalls LIAISON	
Exploring synergies	**How can LIAISON be of help?**	**+/- 15 mins**
	How can policy/standard makers be of help?	
	Views on long-term cooperation and feasibility	
Moving forward + wrap-up	**Next steps LIAISON**	**+/- 15 mins**
	Action-points meeting	
	Follow-up	

Table 4: Meeting agenda exploratory meeting 3 with representatives of the EC.