

A Barbell Strategy-oriented Regulatory Framework and Compliance Management^{*}

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Abstract. As we are witnessing nowadays with self-driving vehicles and robots performing collaborative tasks, and as it has been witnessed in the past, a disruptive technological innovation may cause a regulatory disruption. As a consequence, established regulatory frameworks need to evolve and, in this evolution process, regulatory excellence is paramount for guaranteeing appropriate risk taking, enabling innovators to innovate while efficiently complying to proportionate regulatory frameworks. In risk management theory, or better, in risk taking theory, Taleb has proposed the Barbell strategy, characterised by maximal certainty/ low risk on one extreme of the barbell, and maximal uncertainty on the other extreme, as a means for developing anti-fragility, i.e., ability to gain from disorder. In this paper, we propose our vision consisting of a Barbell strategy-oriented regulatory framework and compliance management, where regulators and manufacturers/innovators, both, adopt a Barbell strategy for reaching an optimal solution in regulatory making, the former, and compliance management, the latter. Finally, conclusion and perspectives for future work are also drawn.

Keywords: Disruptive technological innovation · regulatory framework · compliance · regulatory disruption · Barbell strategy.

1 Introduction

As we are witnessing with nowadays disruptive innovations, e.g., with self-driving vehicles, but also with the development and adoption of robots capable of performing collaborative tasks, in which they work side-by-side (located within the same safeguarded space) with human operator(s) rather than replacing them, and as it has been witnessed in the past, a disruptive technological innovation may cause a regulatory disruption. When regulatory disruption occurs, established regulatory frameworks need to evolve. During such evolution process, regulatory excellence is paramount for guaranteeing appropriate risk taking, enabling innovators to innovate while efficiently complying to proportionate regulatory frameworks.

As depicted in Fig. 1, during such evolution process, two actors play a crucial role: regulators/assessors/standardisation bodies on one side and manufacturers/suppliers on the other side. Both actors analyse the disruptive innovations

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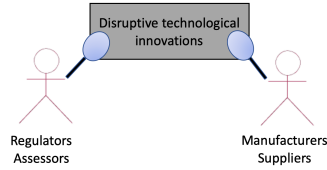


Fig. 1. Actors analysing disruptive innovations.

to contribute to designing the needed changes for its acceptable deployment within society. As Fig. 1 depicts, the two actors compete but also cooperate for the identification of a proportionate regulatory framework.

In risk management theory, or better, in risk taking theory, Taleb [34] has proposed the Barbell strategy, characterised by maximal certainty/ low risk on one extreme of the barbell, and maximal uncertainty on the other extreme, as a means for developing anti-fragility, i.e., ability to gain from disorder. In this paper, we propose our vision for handling the impact of disruptive technological innovations on regulatory frameworks and compliance management. Our vision consists of a Barbell strategy-oriented regulatory framework and compliance, where regulators and manufacturers, both, adopt a Barbell strategy for reaching an optimal solution in regulatory making (the former) and compliance management (the latter). Then, we sketch a roadmap for future research. The rest of the paper is organised as follows. In Section 2, we provide essential background information. In Section 3, we propose our vision. In Section 4, we explain the synergy with the SPI Manifesto. In Section 6, we briefly discuss related work. In Section 6, we propose our intended research agenda. Finally, in Section 7, we present our concluding remarks.

2 Background

In this section, we present essential background information on regulatory frameworks and excellence, regulatory compliance management, disruptive technological innovations and regulatory disruption.

2.1 Regulatory frameworks and excellence

Regulators need to adopt a pro-innovation culture, i.e., rather than adopting an inflexible and pernicious “by-the-book” mentality, regulators are expected to design regulatory processes which mirror the phases of growth of technological innovations. In [8], key facets of a regulator’s organisation and actions that affect its performance are identified. These key facets are internal management; external engagement; priority-setting/decision-making; and problem-solving. In the context of this paper, we recall:

- “Priority-setting/decision-making. An excellent regulator should rely consistently on careful, evidence-based decision making and should set priorities

informed by consideration of risks. An excellent regulator should also be clear about which policy principles it uses when choosing how to prioritise different risks and make decisions.

- Problem-solving. Flexible regulatory approaches promise more cost-effective outcomes, as they give regulated entities the opportunity to choose lower-cost means of achieving regulatory outcomes. [...]. But flexible instruments will not work well under all circumstances. The ultimate test for problem-solving lies in finding the right tool for the purposes and circumstances at hand.”

2.2 Regulatory compliance management

In this subsection, we recall fundamental definitions concerning regulatory compliance management.

Compliance - this term refers to conformance to a rule, such as a specification, policy, standard or law [28].

Regulation - this term refers to the diverse set of instruments by which governments establish requirements for enterprises and citizens. Regulations include laws, formal and informal orders, subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers [28].

Regulatory Compliance - this term refers to obedience by the target population(s) with regulation(s) [28].

Compliance Management - refer to the consistency between the actual development process and the normative reference model embedded in the standard [10]. As presented in [14], compliance management can be handled in various ways. In the remainder of this section, we recall automated compliance by design (compliance checking) and argumentation.

Compliance by Design - approach that provides the capability of capturing compliance requirements through a generic modelling framework, and subsequently facilitate the propagation of these requirements into the process models [32]. The automation of this approach (automated compliance by design, i.e., compliance checking) has been designed [18] and implemented [17] and demonstrated for business processes. Compliance by design has also been further developed and demonstrated in the context of safety-critical systems engineering [2, 5–7, 4]. A personal opinion survey about its relevance has also been conducted [3].

Argumentation about compliance consists in formulating an argument for justifying the claims about compliance. The argument shows the reasoning that connects the claims with the supporting evidence. Automatic generation of arguments is an active research topic (the reader may refer to [11–13, 35] in case of interest in automatic generation of arguments for process compliance). It however requires stable and broadly accepted reasoning strategies. In the absence of broadly accepted reasoning strategies, arguments are typically the result of manual elaboration.

2.3 Disruptive technological innovations and regulatory disruption

Certain technological innovations can undermine existing products, firms, or even entire industries. When this occurs, they are labelled as disruptive. As a consequence of disruptive technological innovations, a regulatory disruption may follow. Specifically, this may happen when the innovation may fall within an agency’s jurisdiction but not square well with the agency’s existing regulatory framework [9]. Regulatory disruption occurs when the “disruptee” is the regulatory framework itself [9]. The introduction of Internet is an example of technological innovation, which caused a regulatory disruption. Nowadays, we are witnessing important technological disruptions. In the automotive domain, the autonomous driving is causing a regulatory disruption and is calling for an urgent solution [1]. A set of standards is being planned [26], while UL 4600 [36] has recently reached a consensus for publication. The key question is understanding what functional safety may mean in case of self-driving vehicles, which, due to the current limitations of machine learning-based algorithmic solutions, may experience black swans [33]. Another key question is understanding how assurance shall be provided [1]. Similar situation can be identified in the context of robots performing collaborative tasks in the domain of collaborative robotics. By 2020, revised versions of ISO 10218-1 [25] and ISO 10218-2 [24] are expected to be published. These revised versions, which build on top of the lessons learnt drawn via the application of the ISO technical specification ISO/TS 15066:2016 [23], define the safety requirements for the sphere of robots expected to perform collaborative tasks (named in non-standardised terminology as COBOTS, collaborative robots). As pointed in [20], besides the robot itself, the robot in this context includes the end effector, i.e. the tool adapted on the robot arm with which the robot performs tasks, and the objects moved by it. Close or direct contact between the robot and the human operator gives rise by definition to a possibility of collision. The robot manufacturer’s risk assessment must therefore also cover the intended industrial workplace. During the transition period triggered by the occurrence of a disruption, as discussed in [9], to face regulatory disruptions, regulators have various means at disposal: inflexible policy making, threats, sunsets. In the first case, regulators persist adopting traditional policy making and this turns out to be premature. In the second case, regulators (representative of a regulatory agency) might announce via guidance document, warning letter, or press release that they will take action against companies that employ novel technologies or business practices in a certain way. Experience has shown that that inflexibility and flexibility via threats are both non viable solutions. Regulators need to decide upon: timing (when to intervene?), form (how to intervene? via adjudication? via guidance? new forms?), durability (how long should the intervention endure? should it be permanent? volatile? e.g., by using sunsets, temporary legislations with finite durations?), and enforcement (how rigorous should be the monitoring of the compliance?). Experience has shown that regulators shall opt for sunset that are binding and enforceable. Sunsets shall be deliberated as early as possible to let them act as stopgap. Sunsets possibly shall be wrapped as regulations or as guidance, practically perceived as binding.

2.4 Taleb’s Barbell strategy

In his book on anti-fragility (property that characterise systems able to gain from disorder, including disorder generated by the occurrence of black swans [33]), Taleb mentions the Barbell-strategy as a means for developing anti-fragility. The Barbell strategy consists of a bimodal strategy, a combination of two extremes, one safe and one speculative. Such bimodal strategy is deemed more robust than a “mono-modal” strategy. Taleb exemplifies the strategy in the financial domain and then illustrates its application in various domains. In the financial domain, a barbell strategy is characterised by maximal certainty/ low risk in one set of holdings, maximal uncertainty in another. More precisely, it consists of the mixing of two extreme properties in a portfolio such as a linear combination of maximal conservatism for a fraction of the portfolio, on one hand and maximal (or high) risk on the remaining fraction. In [15], the Barbell strategy is formalised and it is demonstrated that it turns out to be an optimal solution.

3 A Barbell strategy-oriented Vision

In this section, we present our vision for an optimal solution consisting of a barbell strategy-oriented regulatory framework and compliance.

3.1 A Barbell strategy-oriented Regulatory Framework

As shown in Fig. 1, both actors, regulators/assessors/standardisation bodies and manufacturers/innovators cooperate/compete to identify a proportionate regulatory framework and compliance management. Based on what recalled in the background, to face disruptions, sunset-based enforceable regulations seem to be the appropriate regulatory tool to face unknown unknown. Thus, in our vision, regulators/assessors/standardisation bodies shall cooperate to propose a barbell strategy aimed at facing known knowns (i.e., innovation-related risk that we know that we know) via traditional portions of regulatory frameworks and facing unknown unknown (i.e., innovation-related risk that we do not know we do not know, the kernel of the disruption) with subset-based regulations or binding guidance. This vision is depicted in Fig. 2.

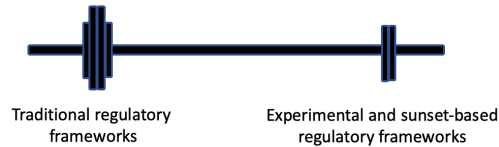


Fig. 2. Barbell strategy-oriented Regulatory Framework.

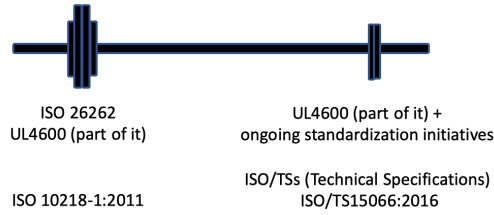


Fig. 3. Regulatory Framework Vision for Robotics and Automotive.

As depicted in Fig. 3, our vision can shed lights on the current development in the automotive and robotics domains. In the automotive domain, road vehicles that have a degree of automation that still squares well with the agency’s existing regulatory framework need to comply ISO 26262 [21]; while road vehicles that have a disruptive degree of automation are expected to comply with UL4600, a binding guidance, result of a consensus-based deliberation process.

In a similar manner, in the robotics domain, robots that have a zero-degree of cooperation (are not located within the same safeguarded space as human operators/are not expected to perform collaborative tasks) still squares well with the agency’s existing regulatory framework and need to comply with ISO 10218-1:2011 [22]; while robots that have a disruptive degree of cooperation (are located within the same safeguarded space as human operators/are expected to perform collaborative tasks) are expected to comply with ISO/TS 15066 [23] and later on with the currently under development ISO 10218-1 [25] and ISO 10218-2 [24], a binding guidance result of a consensus-based deliberation process. These dual strategies are aligned with our vision.

3.2 A Barbell strategy-oriented Compliance Management

As recalled in Section 2, compliance can be managed via different approaches with different degrees of automation. On one hand, compliance by design is time-consuming given the considerable effort required during the formalisation process. However, this solution seems promising in terms of return on investment especially within stable regulatory frameworks, where rules are known and also the corresponding allowed interpretations. On the other hand, argumentation, mainly formulated in natural language, is mainly conducted manually. Argumentation offers a possibility for negotiating via the elaboration of compelling arguments which may go beyond traditional ways of doing. Thus, our Barbell strategy-oriented compliance management vision is depicted in Fig. 4.

3.3 Discussion

Our vision based on a double Barbell strategy applied to regulatory frameworks and compliance management has the potential to increment a dialogue between the parties and ease the exploitation of the best practices allowing parties taking

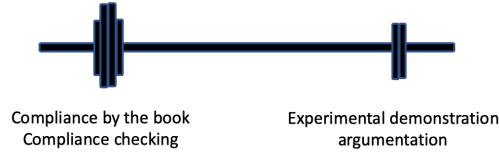


Fig. 4. Barbell strategy-oriented Compliance Management.

advantage of the opportunities inherent proven/mature best practices, while actively searching for solution on how to handle the disruption.

4 Synergy with the SPI Manifesto

The SPI Manifesto targets software. Our vision is not limited to software, it embraces disruptive innovations in general. Software process improvement is highly connected to the regulatory framework, which may constrain it. In our vision, we do not only focus on the improvement of the process adopted by the innovator(s) to develop their software but also on the process adopted by the regulator. Our vision could be seen as a generalisation of the SPI Manifesto to a PI. Specifically, we see that our Barbell strategy-oriented vision pursues a bimodal strategy that preserves useful portions of regulatory frameworks and discard what is not applicable anymore, replacing it with risky but temporary and dynamic solutions. Thus, it can be seen in synergy with principle 6 of the SPI Manifesto [29], which states “use dynamic and adaptable models as needed”. As quoted in Section 6.1 of the SPI Manifesto, “All models are wrong - some are useful”. The best practices can be replaced by new practices, recognised as potential new best practices or pioneering practices. In addition, our vision is strongly related with principle 7 of the SPI Manifesto, which states “apply risk management”. Our vision is an exploration of the risk management, which includes risk taking towards an optimal solution for handling disruptive innovations, in line with the recently proposed manifesto for antifragile software [30]. Finally, our vision is also strongly related with principle 8 of the SPI Manifesto, which states “Manage the organisational change in your improvement effort”. A disruptive innovation represents a change.

5 Related work

To the best of our knowledge, our work represents a novelty since no research so far has been conducted to elaborate a Barbell strategy-oriented perspective on regulatory frameworks and compliance management to handle disruptions. A conceptual exploration of a Barbell strategy has been conducted in the context of agile development and education. Specifically, in [19], it is proposed that the agile enterprise portfolio executes on proven business opportunities while actively embracing change and uncertainty. In [27], a Barbell strategy is explored

in the context of Asian countries, where students aim for academic excellence, risking psychological diseases. The strategy allows for maintaining a trajectory of academic excellence while avoiding the psychological pressures, which usually accompany Asian students.

6 Research roadmap

In this section, we present our intended research roadmap, expected to be addressed within the SACSys (Safe and Secure Adaptive Collaborative Systems) project [31] in collaboration with the Volvo Group Collaborative Robot Systems Laboratory [16]. Within this project, design and runtime compliance of collaborative systems is in focus. Given the disruptive nature of the type of systems proposed by the case study owners (i.e., 1) self-driving vehicles in quarry sites cooperating with manned vehicles and 2) robots performing collaborative tasks within a manufacturing factory), and given the ongoing regulatory disruption within the automotive and robotics domain, we intend to analyse the ongoing changes within the standards that are under discussion in order to design our barbells. Specifically, we need to identify which parts of the standards represent the maximal certainty (known knowns)/ low risk and which parts represent the maximal uncertainty (unknown unknowns). Once this is identified, in cooperation with the industrial partners and regulators in the automotive and robotics domains, we will design a series of case studies to explore the possible benefits of having a bi-modal strategy-oriented for the regulatory frameworks on one side and a bi-model strategy-oriented compliance management on the other side. The goal would be to show that it could turn out to be an optimal solution to combine traditional and binding regulatory frameworks with experimental and sunset-based regulatory frameworks on one side and compliance by the book (via compliance checking) and experimental demonstration (via argumentation) on the other side. Our research will also target the elaboration of heuristics for distributing the weights on the two extremes. Initially, the focus will be on process-related requirements and then it will be extended to product-related requirements.

7 Conclusion

In this paper, we have presented our vision for an optimal solution for handling disruptive technological solutions impacting regulatory frameworks and compliance management. Specifically, after having introduced a broader perspective on the impact and state of the art practices in handling corresponding disruptive consequence within regulatory frameworks and compliance management, we have proposed our Barbell strategy-oriented vision and our research roadmap towards the concretisation of our vision.

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