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# When risks cannot be seen: Regulating uncertainty in emerging technologies

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## ABSTRACT

Commercializing an emerging technology that employs an immature production process can be challenging, particularly when there are many different sources of uncertainty. In industries with stringent safety requirements, regulatory interventions that ensure safety while maintaining incentives for innovation can be particularly elusive. We use the extreme case of metal additive manufacturing (an emerging technology with many sources of process uncertainty) in commercial aviation (an industry where lapses in safety can have catastrophic consequences) to unpack how the characteristics of a technology may influence the options for regulatory intervention. Based on our findings, we propose an adaptive regulatory framework in which standards are periodically revised and in which different groups of companies are regulated differently as a function of their technological capabilities. We conclude by proposing a generalizable framework for regulating emerging process-based technologies in safety-critical industries in which the optimal regulatory configuration depends on the industry structure (number of firms), the performance and safety requirements, and the sources of technological uncertainty.

## 1. Introduction

New manufacturing techniques bring challenges associated with their technological uncertainty, which requires the development of process understanding and control procedures to transition “from art to science” (Bohn, 2005). This can be critical to broader commercial viability and adoption. Examples in the literature include biotechnology (Pisano, 1991), chemicals and pharmaceuticals (Pisano, 1997; Straathof et al., 2002), semiconductors (Bassett, 2002; Bohn, 1995; Holbrook et al., 2000; Lécuyer, 2006), optoelectronics (Fuchs and Kirchain, 2010) or aircraft manufacturing (Mowery and Rosenberg, 1981).

Traditionally, approaches to regulate risk have been divided into technology-based, performance-based and management-based regulation (Coglianese et al., 2003). Each approach incentivizes a different level of innovation at firms, and tackles technological uncertainty in a different way. Technology-based regulation decreases uncertainty by mandating the use of a certain technology, but may limit innovation and the adoption of new technologies and processes (Dudek et al., 1992; Jaffe and Stavins, 1995; La Pierre, 1976; Stewart, 1991). Performance-based regulation allows firms greater opportunities for innovation, but it does not work well when it is difficult to demonstrate that the desired performance has been achieved (Coglianese et al., 2003; Downer, 2007; Notarianni, 2000). Management-based regulation aims to shift the decision to the actor with the most information (Coglianese and Lazer, 2003; Downer, 2010). Such actors have a better understanding of the risks and benefits of the technology. However, implementing management-based regulation is more difficult than the other approaches, and history shows that engineers may underestimate risks (Petroski, 1992). Independent of the approach taken to regulating them, the emergence of new and uncertain technologies such as biotechnology, nanotechnology or climate change mitigating technologies, has led to an increasing demand for adaptive regulation that is periodically revised to ensure that it updates its content to incorporate the latest available knowledge (McCray et al., 2010; Oye, 2012; Wilson et al., 2008).

We use metal additive manufacturing (MAM), an example of an emerging technology with many sources of uncertainty; and civil aviation, an industry with stringent safety standards but for which MAM promises many performance benefits, to analyze regulatory needs as a function of technological uncertainty. We triangulate archival data, 37 semi-structured interviews, and 80 hours of participant observations

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(Jick, 1979), including insights from an invitational workshop we ran in Washington, D.C. with 25 leaders from government, industry and academia. We use grounded theory-building methods (Eisenhardt, 1989; Glaser and Strauss, 1967) to reveal the process by which MAM and other technologies are regulated in commercial aviation, and the complex intertwine between innovation and uncertainty.

We find that there are still many sources of uncertainty surrounding MAM in terms of material supply, equipment configuration, process control, and post-processing procedures. In an industry such as aviation with a marked "learning by using" component, some of this uncertainty may only be revealed with flight experience. There are also important differences across the supply chain in terms of knowledge, financial resources, goals, and regulatory oversight which may result in additional sources of risk. Current certification procedures are not well-suited to dealing with this uncertainty and to the variation in competence across the industry. At the same time, currently proposed mechanisms to regulate MAM products may affect the long-term competitiveness of the technology. To balance the need for safety and innovation, new adaptive regulation mechanisms are needed for when the technology is still immature.

This paper contributes to the literature by clarifying how, for a specific emerging technology, different sources of uncertainty may change the optimal regulatory design. In addition, we show how the differences in their underlying motivations and technology capabilities across supply chains may create the need for additional collective action to ensure an adequate level of safety. We leverage the extreme case of MAM in civil aviation. Iterating between our findings and existing theory on technological uncertainty and the regulation of technological risks, we propose a new typology for considering the regulatory tradeoffs between safety and the sources of technological uncertainty across different technologies and industries.

## 2. Literature review

### 2.1. Technological uncertainty in immature technologies

Development of an emerging technology is marked by a progressive decrease in the levels of technological uncertainty and variability in the production outputs, a transition which Vincenti (1990) coined as "from infancy to maturity" and Bohn (2005) as "from art to science".[1] Examples of industries where these uncertain maturation processes have been paradigmatic include biotechnology (Pisano, 1991), chemicals and pharmaceuticals (Pisano, 1997; Straathof et al., 2002), semiconductors (Bassett, 2002; Bohn, 1995; Holbrook et al., 2000; Lécuyer, 2006), optoelectronics (Fuchs and Kirchain, 2010) and aircraft manufacturing (Mowery and Rosenberg, 1981). These examples are notably dominated by chemical- and advanced-material-based products, as well as in the case of aircraft manufacturing, complex, multi-part interdependent systems.

In the early years of an emerging technology, scientists often have difficulty explaining why a particular piece of equipment or process does or does not work as expected. Production yields are low due to the inability of establishing robust relationships between production inputs and outputs. There is also a lack of adequate process control (Bohn, 1995); Learning which production step is the cause of such variability can be slow (Balconi, 2002). For instance, Collins (1974) explains how in the early stages of the development of laser technology, a group of scientists made what appeared to be an exact replica of a working laser, yet failed to make it work and finally gave up.

As experts start accumulating knowledge, they forge intuitive models about the underlying mechanisms that govern the processes and begin to implement some amount of process control. At this stage, similar to traditional crafts in which apprentices learn from their masters (Bohn, 2005), knowledge is mainly tacit (Polanyi, 1958) and thus results cannot easily be replicated even within the same firm, and often less in an outside firm (Teece et al., 1997). Yields improve as knowledge is created, but when the science of production at large volumes is fundamentally different than that at small volumes, it may still not be good enough for commercialization (Pisano, 1997). The same may be true if the emerging technology is unable to be profitable against the incumbent technology given consumer preferences in present-day markets (Fuchs and Kirchain, 2010). Even when knowledge improves through experience to the point that it can be codified, as for example in the form of checklists and standard operating procedures, it may take a long time for the basic underlying science to be understood well enough for that knowledge to be applied in contexts that are substantially different from those in which the experience was gained (de Solla Price, 1984; Semmelweis and Murphy, 1981). Often only after the development of theories and mathematical models to explain the behavior of the technology, is knowledge generalized such that results can be systematically replicated, arriving at what Bohn (2005) calls "science."

During the maturation period, firms may acquire knowledge in a different manner which allows them to control the sources of uncertainty and reduce manufacturing costs. For the design of complex parts, Fleck (1994) describes a process he calls 'learning by trying', in which engineers perform small changes to the constituents until a final working configuration is achieved. Similarly, in the context of manufacturing, Arrow (1962) describes a process he calls "learning by doing" in which through repeated experience producers become familiar with the problems that arise during the manufacturing process and are able to implement slight modifications. In the context of aircraft manufacturing, Wright (1936) proposed one of the first models of a "learning curve," an empirical relationship between the number of units produced and a decline in unit cost. Nevertheless, some aspects of a technology may only be revealed in the use phase of the final product, due to the inability to cost-effectively simulate those conditions (or the length of exposure thereto) in a test environment. This 'learning by using', had a central role in reducing uncertainty about the performance of new aircraft in the early 20th century (Mowery and Rosenberg, 1981). Learning by using has proved particularly important in reducing the uncertainty surrounding new materials like advanced composites in aircraft (RAND, 1992). Learning by using sometimes reveals unexpected behaviors like the propagation of fatigue cracks that occurred along the square-shaped advanced windows of the De Havilland Comet aircraft, and which led to a series of catastrophic accidents (Withey, 1997). Downer (2011a) coined the term "epistemic accidents," defining them as 'accidents that occur because a scientific or technological assumption proves to be erroneous, even though there were reasonable and logical reasons to hold that assumption before (although not after) the event.' Epistemic accidents are unpredictable and more likely to occur when working with emerging technologies (Downer, 2011a).

The speed at which technology is able to mature from art to science is affected by both its particular characteristics and by contextual factors. Technology characteristics include the number of input variables and their interaction (Macher, 2006), the total number of parts (Singh, 1997), the total amount of information (von Hippel, 1994), the existence of appropriate measurement techniques (Brown and Duguid, 2001), and the ability to test during intermediate production stages (Lécuyer, 2006). Furthermore, innovation in the form of new procedures (Fleck, 1994; Pisano, 1997), new process control mechanisms (Hatch and Mowery, 1998) and complementary technologies such as specific testing equipment (Lécuyer, 2006) are normally needed to reduce variability in manufacturing. Examples of contextual factors affecting technology's evolution are technological diversity (David and

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[1] The transition described by Bohn (2005) is closely related to the classic literature of product life-cycle, including the dynamics of product and process innovation (Gort and Klepper, 1982; Utterback and Abernathy, 1975; Vernon, 1966). These papers put more focus on the implications of the dynamics of technological change for industry structure and entry and exist of firms, as well as the destruction of established ones. As we are more focused on the evolution of technological uncertainty in manufacturing, we focus our discussion more around the literature by Bohn (2005) and Vincenti (1990).

Rothwell, 1994), scale (Slayton and Spinardi, 2015), the situated nature of adaptive learning (Fuchs and Kirchain, 2010; von Hippel and Tyre, 1995) and user accessibility (von Hippel, 1976).

When it is successful, the learning and convergence processes described above ultimately lead to the standardization of a technology, which can provide substantial benefits to firms by reducing uncertainty. However, in the case of a rapidly evolving technology, it can also trap firms in an obsolete standard (Farrell and Saloner, 1985). This potential for becoming trapped in a sub-optimal solution creates a difficult relationship between standardization and innovation (Allen and Sriram, 2000). Overcoming this trap may require an evolutionary regulatory approach over the course of the life cycle of the technology to avoid early inhibition of innovation (Tassey, 2000). Technological diversity − that is, having a variety of strategies to solve a certain technological problem − can be important when a field is immature and uncertainty about the final performance of each solution is high (Holbrook et al., 2000). As uncertainty decreases, replicability (within a firm or between firms) can be improved through the implementation of shared practices which facilitate knowledge transfer (Brown and Duguid, 2001).

Based on the literature, we define an immature technology as one which has not yet made the transition from art to science (e.g., Vernon, 1966; Collins, 1974; Teece et al., 1997; Pisano, 1997; Bohn 2005).

### 2.2. Regulation of technological uncertainty

From a regulatory perspective, there are several options to manage the uncertainty posed by an immature technology. Coglianese and Lazer (2003) divided regulatory intervention into management-based, technology-based, and performance-based regulation, depending on whether it targeted the planning, acting, or the outcome stage in the production process, respectively.

Technology-based regulation mandates the adoption of a certain technology to achieve a certain regulatory objective. Although regulation may in principle give firms some flexibility to achieve compliance through several different technologies or strategies, firms frequently have strong incentives to conform in adopting a particular solution (Stewart, 1991). For example, the Environmental Protection Agency (EPA) standards often define a “best practicable technology” assessing both the effectiveness in reducing pollution and the implementation cost for firms (McCubbin, 2005). Such behavior has been seen in diverse fields like pollution control in the Clean Air and Clean Water Acts (La Pierre, 1976; Maloney and McCormick, 1982; Shapiro and McGarity, 1991; Wagner, 2000), and also in occupational health and safety (Maloney and McCormick, 1982; Wagner, 2000).

Claimed advantages of technology-based approaches include the possibility of a higher-than-market valuation of non-market goods (Shapiro and McGarity, 1991; Viscusi, 1983), the reduction of equity problems (Shapiro and McGarity, 1991), the reduction of the needs for monitoring (Wagner, 2000), ease of promulgation, and superior enforceability (Wagner, 2000). Although it has been argued that firms under a technology-based environment still have incentives to develop new technologies to meet the targets more efficiently than with the available technology (Wagner, 2000), a wide body of literature suggests that firms may have less incentives to innovate and go beyond compliance (Dudek et al., 1992; Jaffe and Stavins, 1995; La Pierre, 1976; Stewart, 1991). This is especially true in contexts where demonstrating success to regulators is particularly burdensome. For instance, the introduction of new nuclear technologies is limited by the unsuitability of current regulation for new nuclear technologies other than light-water reactors, the currently dominant technology (Lester, 2016). Thus, competing technologies which are not endorsed by the regulation, but which nevertheless might be more efficient in accomplishing the regulatory goals, may lose an important market for their development (Stewart, 1991). Other disadvantages are that implementation costs might be higher than the benefits provided by the new technology (Shapiro and McGarity, 1991; Stewart, 1991); and the suboptimal character of applying the same technology for everyone, without accounting for the differences between players (Stewart, 1991).

Performance-based regulation (including, but not limited to, performance-based standards) mandates a certain outcome, but does not specify how that outcome must be achieved (Coglianese et al., 2003; Spogen and Cleland, 1977). Such standards give manufacturers the flexibility to choose the solution they prefer. For instance, the Federal Aviation Administration (FAA) requires that aircraft taking off be capable of achieving a minimum climb rate (14 CFR 25.111), but engine and aircraft manufacturers have the freedom to design any product capable of achieving that rate. Other industries which have adopted performance-based standards include automotive (Vinsel, 2015), food (Henson and Caswell, 1999), electric utilities (Sappington et al., 2001) and building safety (May, 2003).

Performance-based regulation can accommodate technological change better than technology-based standards, and may help draw more attention to the real objectives and levels of uncertainty (Coglianese et al., 2003). However, this approach presents challenges when the standards are not well-defined, performance is difficult to measure, or there is a high level of uncertainty in the relationship between the outcome level and the risk it poses (Coglianese et al., 2003; Notarianni, 2000). One example is the testing of jet engines for bird strikes, which the FAA (2014) estimates costs hundreds of millions of dollars and hundreds of thousands of hours of aircraft downtime (FAA, 2014a) annually in the U.S. Many problems arise in trying to define a test to replicate these real life situations (Downer, 2007). Even when there is agreement that the tests appropriately simulate the actual event, and the engine performs adequately, there can be disagreement about what constitutes the worst case scenario. For example, the highest-speed impact may in some cases do less damage than a low-speed impact. Given that each such test would do substantial damage to a jet engine, exploring the entire envelope of possibilities (including, for example, size and velocity of the bird, point of impact, engine fan speed at impact) can be prohibitively expensive. As such, even defining the appropriate performance standard requires a judgment call (Downer, 2007). In addition, performance-based standards increase the monitoring costs (Coglianese et al., 2003) and often suboptimal standards are achieved depending on agency implementation procedures (Gaines, 1976).

In management-based regulation, or “enforced self-regulation” (Ayres and Braithwaite, 1995), the government requires “a range of processes, systems, and internal management practices” of private firms (Coglianese and Lazer, 2003). Instead of defining specific technologies to use, or outputs to achieve, firms establish their own internal plan and standards to achieve goals defined by the regulators (Coglianese and Lazer, 2003; Gunningham and Sinclair, 2009). A variant to the concept of management-based regulation is “meta-regulation” (Gilad, 2010; Parker, 2002), in which firms are expected to provide regulators with continuous evaluation of their compliance systems so as to enhance regulators’ knowledge (Gilad, 2010). The primary role of regulators is not to check direct compliance with legislation, but rather to audit the corporate management systems, and in some cases to review documentation provided by the firm to show compliance (Coglianese and Lazer, 2003; Gunningham and Sinclair, 2009). In aviation, for example, manufacturers employ designees whose mission is to bridge the gap between the regulator and the regulated, and provide authorities with information regarding manufacturing activities (Downer, 2010). Similar approaches have been implemented in food safety (Coglianese and Lazer, 2003; Henson and Caswell, 1999), environmental safety, like the Massachusetts Toxic Use Reduction Act (Coglianese and Lazer, 2003), and occupational health and safety (Gunningham and Sinclair, 2009; Hutter, 2001).

Management-based regulation can be an appropriate approach when regulatory outputs are relatively difficult to monitor, moving the locus of decision-making towards the players who possess the most information (Coglianese and Lazer, 2003). They can also be particularly effective when firm incentives are aligned with regulatory incentives — for example, lethal or highly disruptive accidents might reduce business for the firm. Management-based regulation provides firms with greater flexibility to respond to changes in technology or safety requirements, especially in cases where internal management is easier to change than federal regulation (Bennear, 2006). For firms, such an approach is usually cheaper than government-imposed standards, and in certain cases, such as in the pharmaceuticals industry, has been shown to be more effective (Ayres and Braithwaite, 1995). Management-based regulation can also create incentives for firms to look for new and more innovative solutions (Coglianese and Lazer, 2003), and ameliorate problems that can arise due to the lack of resources at public agencies (Coglianese and Lazer, 2003). Finally, compliance might be higher if employees perceive internal rules as more reasonable than external rules (Ayres and Braithwaite, 1992; Kleindorfer, 1999).

However, management-based regulation also has drawbacks. Experience suggests that engineers can underestimate the technological risks in their new designs (Petroski, 1992), which might not be detected by the authorities. Furthermore, implementation requires a far more complex relationship between regulators and the private sector (Coglianese and Lazer, 2003), and there is higher danger of regulatory capture (Downer, 2010). To be effective, management-based regulation requires internalization of the rules across the entire company (Gilad, 2010), and faces the risk of those internal rules being broken by employees (Hutter, 2001). The implementation of such internal rules might not be suited for small organizations with limited resources (Fairman and Yapp, 2005), and be very complex in large organizations (Haines, 2009; Hutter, 2001).

Choosing a path that strikes the right balance between safety and technology adoption is a complex dance between companies, non-corporate players such as academics with deep technical knowledge, industry standards bodies incentivized to commercialize those technologies, and regulators whose job is to focus on safety rather than to facilitate the adoption of new technology. These regulators are incentivized to reduce risks by adopting defensive postures following the "precautionary principle" (Kriebel et al., 2001; Sunstein, 2005), which states that, if an activity poses a potential public risk, in the absence of scientific consensus, the proponent of such activity must bear the burden of proving that it poses an unacceptable risk.

To achieve the right balance between technology innovation and risk mitigation, Mandel (2009) has made a series of recommendations, including: the promotion of data gathering and sharing, the avoidance of regulatory gaps, the promotion of knowledge and collaboration across agencies, and the provision of adaptive regulation. Making data public can also force firms to improve compliance due to increased public pressure, as happened after EPA released the Toxic Release Inventory in 1989, the release of which information caused important financial losses to companies with higher pollution (Hamilton, 1995). Regarding adaptive regulation, Van Calster (2008) explains in the context of technologies to combat climate change: "over-reliance on one instrument, especially in the early stages of regulatory design, prevents the benefits of trial and error." In an industry with stringent certification procedures like pharmaceuticals, Yu (2008) argues that traditional approaches to quality control may be hindering quality and performance by restraining flexibility in manufacturing process and testing. Rathore and Winkle (2009) suggest that the uncertainty surrounding regulatory aspects of new pharmaceutical technologies causes reluctance among manufacturers to adopt innovations. This need for adaptive regulation with transparent procedures and timelines has been recognized in other new fields of knowledge like biotechnology and nanotechnology which may pose unknown health and environmental risk to society (Levidow et al., 1996; Lin, 2007; Mandel, 2009; Oye, 2012), and climate change mitigation (Wilson et al., 2008).

Regardless of the regulatory approach taken, the writing and enforcement of regulation regarding emerging technologies takes place in the presence of significant uncertainty, and requires substantial regulator discretion. Unfortunately, regulators may not have sufficient knowledge to adequately exercise such discretion (Blayse and Manley, 2004; Chan et al., 1995; Downer, 2010). For instance, in the context of environmental science, data used for policy-making are frequently limited by uncertainty about the associated risks and costs, leading to "gray areas" where policymakers must exercise their judgment (Kriebel et al., 2001; Stone, 2002). Within these uncertain areas, "street-level bureaucrats" (Lipsky, 1980) such as the officials in charge of checking compliance at a manufacturing facility, have a relatively high level of discretion to interpret and enforce the rules (Evans and Harris, 2004; Lipsky, 1980). Street-level bureaucrats act according to a set of tacit rules, which evolve as they face new situations and interact with their colleagues, helping spread new rules across the organizations to which they belong (Piore, 2011; Piore and Schrank, 2008). In local communities, the adoption of "problem-oriented policing" strategies, which rely on officials to proactively identify new problems, has helped reduce crime (Goldstein, 1990). While too much discretion is undesirable because it can lead to a loss in agency accountability, Susskind and Secunda (1998) argue that to promote technological and regulatory innovation, agencies should allow greater discretion by regulators on the ground.

Even in the case of technology-based regulation, which substantially limits regulators' discretion by narrowly identifying the technological option to implement (Wagner, 2000), dialogues between the regulator and the regulated take place. Latin (1991) explains how EPA officials, forced to apply a technology-based standard without having had time to acquire the proper technical knowledge and skills, ended bargaining with each company to determine the appropriate measures and implementation timeline to comply with the Clean Air Act. In the case of performance-based regulation, the level of discretion possible depends on how precisely the rules are defined (Coglianese et al., 2003). For management-based regulation, negotiation processes are paramount. This strong social and moral dimension may raise concerns about the susceptibility of regulatory agencies to "regulatory capture" by manufacturers in industries with powerful interest groups, which may introduce additional risks when manufacturers' risk tolerance is affected by market pressures (Dana and Koniak, 1999; Downer, 2010). To reduce the risks of capture, Ayres and Braithwaite (1995) argue that the participation of public interest groups, assuming that there are groups in the required technical domain, is vital in the regulatory process, although these groups might also be captured. An example of a such group with technical expertise and strong legal capabilities is the Environmental Defense Fund (Esty, 2000).

Literature on the regulation of technological risks (e.g., Coglianese and Lazer, 2003; Gilad, 2010) lays out the advantages and disadvantages of the different types of regulatory approaches. In contrast, adaptive regulation (e.g., Wilson et al., 2008; Mandel, 2009) offers a series of policy mechanisms to balance technology uncertainty and the need for innovation, independent of regulatory style. Currently, both literatures treat all technologies equally, missing the links between the characteristics of a technology and the type of regulation. There is also little work on how these regulatory approaches apply to a situation where stakeholders in the industry have different capabilities. Our work presents a new typology for regulation to take into account a technology's maturity as well as variance in capabilities across industry structure, to achieve a regulator's desired balance between safety and innovation.

## 3. Methods

We conduct inductive research to "(1) enable predication and explanation of behavior, and (2) be useful in theoretical advance [in the social sciences]" (Glaser and Strauss, 1967). In theory, we seek "a story about why acts, events, structure, and thoughts occur" (Sutton and Staw, 1995), "the model of that portion of the socioeconomic world which the participants themselves use in making decisions…, [and] models that… [represent] direct reflection of reality" (Piore, 1979).

Following grounded theory-building, we "compare systematically the emergent frame with the evidence from each case in order to assess how well or poorly it fits with case data…. constantly compare theory and data − iterating towards a theory which closely fits the data" (Eisenhardt, 1989). We focus on the theoretical insights possible from a single, unusually revelatory and rich case (Yin, 2013; Eisenhardt and Graebner, 2007; Gersick, 1994; Hargadon and Douglas, 2001; Mintzberg and Waters, 1982).[2] While some single-case study research focuses on a case of success (Galunic and Eisenhardt, 2001; Galunic and Eisenhardt, 1996; Hargadon and Sutton, 1997; Mintzberg and Waters, 1982), we focus on an extremely constrained case, in the interest of shedding insight into the implications for other contexts where one or more of those constraints might be removed. Other such examples of focusing on a constrained case include Fuchs and Kirchain (2010), Fuchs (2014) and Rosenkopf and Tushman (1998). In contrast to examples which focus on an individual (Ibarra, 1999), organization (Gibson and Smilor, 1991; Hargadon and Sutton, 1997), region (Avnimelech and Teubal, 2006; Piore and Schrank, 2008), or nation (Wonglimpiyarat, 2016; Zhao and Aram, 1995) as the unit of analysis, our unit of analysis is the emerging technology itself (Becker, 2013; Collins, 1974; Fuchs and Kirchain, 2010) in a particular industrial context (Bernstein and Singh, 2006; Holbrook et al., 2000) (and in this paper, one that is particularly stringent or constraining).

Our specific case is metal additive manufacturing (an emerging technology) in the context of the civil aviation industry. We use grounded theory-building methods (Eisenhardt, 1989; Glaser and Strauss, 1967) to gain insight into technological uncertainty and the regulatory process in this immature technology in this safety-critical industry. We triangulate archival data, 37 semi-structured interviews, and 80 hours of participant observations (Jick, 1979). As part of our participant observations, we ran a day-long, invitation-only expert workshop (See Tables 1,4,5).

Aeronautics is an industry characterized by a high degree of tacit knowledge (McNichols, 2008), making interviews with industry insiders a critical source of insight and data. The thirty-seven interviews constituted our primary source of information, and helped us identify the focal themes of our study. We selected our interviewees with the goal of gaining insights from the full range of stakeholders in the regulatory process: Engine and Aircraft Original Equipment Manufacturers (OEMs), Suppliers, MAM Equipment Manufacturers, Public Agencies, and Research Centers. Continuous communication with various FAA officials has helped us gain a deeper understanding of the development of certification practices and of how past experiences with composite materials or powder metallurgy might affect the Agency's attitude towards MAM. We complement the insights from the interviews with archival data (Table 1). In Table 1, we group our archival data into different subcategories: FAA regulation, orders, and advisory material; international agreements; other industry/government reports; press releases, and technical documents about MAM.

In addition, we conducted participant observations at several meetings and project reviews organized by America Makes, the National Advanced Manufacturing Innovation Institute. This consortium includes representatives from government, industry, and academia. Through our collaboration with the additive manufacturing laboratory at Carnegie Mellon University, we have also been able to directly observe, and interact with, MAM experts using the machines, and thereby gain knowledge of the technical nuances of different AM processes. Finally, as noted above, on June 19th 2015, we organized a closed-door meeting in Washington, D.C. with 25 leaders from government, industry and academia in which participants discussed how to overcome the challenges of technology introduction, material process qualification, and other technological and regulatory challenges. The meeting, which we ran under Chatham House Rules[3] to foster openness in the discussion of delicate policy issues (Corner, 2013; Petticrew et al., 2004), helped us gain greater understanding of the issues at play in the industry and the advantages and disadvantages, as perceived by industry stakeholders, of potential solutions to the challenges in regulating an emerging technology like MAM.

## 4. Findings

### 4.1. Private and public interest in promoting metal additive manufacturing in aviation

MAM is a family of near net shape manufacturing processes in which digitally created three-dimensional objects can be built up by depositing material in successive layers. "Near net shape" means that the geometry of the product after the primary production process is very close to the final shape, although it still requires some removal of material afterwards. In contrast to "subtractive" processes, which remove material to create a shape, "additive" manufacturing processes, by building the shape layer by layer, generally have less material waste. Although there are multiple MAM technologies, the most commonly used in aeronautics are powder bed fusion systems. In powder bed fusion, consecutive layers of powder with a thickness of 100 micrometers or less are deposited while a heat source melts the material only in those areas which correspond to the desired geometry. This heat source can be a laser, in which case the process is called Direct Metal Laser Sintering (DMLS), or an electron beam, in which case the process is called Electron Beam Melting (EBM). The distribution and melting of the powder to achieve the desired "near net shape" occurs inside a closed chamber with an inert atmosphere to reduce impurities in the final product. Private and public parties around the globe interested in building, maintaining and strengthening their national comparative advantage in manufacturing are eager to promote MAM's adoption (European Commission, 2014). To that end, in 2012, the U.S. saw the creation of America Makes, the National Additive Manufacturing Innovation Institute.

Aeronautics is an industrial sector which could greatly benefit from MAM adoption because it involves low-volume, high-value products which need to be lightweight. While important in its own right, the aviation industry is also central to national economic and military competitiveness. In the U.S., civil aviation represents more than 5% of the GDP, supports more than 11 million jobs and is the greatest net export (FAA, 2014b). Several aeronautical manufacturers are active members of America Makes, as is the Department of Defense, spearheaded by the U.S. Air Force. As well as being customers, their involvement represents an important source of funding of America Makes.

The use of MAM in aviation could lead to substantially shorter development times (GE, 2015a); the repair and production of parts in the field; reduced material use (Harris, 2011); and light-weighting and reduced aircraft fuel consumption, this last which accounts for about 30% of airlines operating costs (Pearce, 2014). However, MAM is still an immature technology, and as such presents significant challenges, including control of variability within and across batches.

This technological uncertainty also creates regulatory challenges in industries where technological risks directly impact safety. Despite MAM's immaturity, several leading commercial aviation manufacturers have started to make parts using MAM. In less than five years, parts

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[2] Yin (2013) writes, "Theoretical sampling of single cases is straight-forward. They are chosen because they are unusually revelatory, extreme exemplars, or opportunities for unusual research access."

[3] "When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed." (Source: http://www.chathamhouse.org/about/chatham-house-rule)

**Table 1**
Summary of archival data sources used in this paper. Full references can be found in the 'Referenced data sources' section at the end of the paper.

| Archival data category | Documents | References |
|---|---|---|
| Aviation industry | Title 14 of the Code of Federal Regulations | §21.97 §21.150 §21.179 §25.603 §25.605 §25.613 §25.621 §33.15 |
| | FAA Orders related to certification procedures | 8100.15, 8120.22, 8110.4C 8110.42D, 8120.23, 8130.2H |
| | FAA Advisory Circulars | 20.613, 21.43, 23.1309-1E |
| | International Agreements | (EASA, 2014; FAA, 2010a; USA and CE, 2011) |
| | Other government/industry reports | (FAA, 2014a, 2014b, 2013, 2009a, 2009b, 2000; GAO, 2013; IATA, 2016; Khaled, 2015, 2014; NTSB, 2013; Pearce, 2014, 2013; PRI, 2016; RAND, 2001, 1992; Simons, 2007; Spafford et al., 2015; Torrey et al., 1989) |
| | Press releases | (Hollinger and Powley, 2015; Ostrower, 2016; Ostrower et al., 2013; Sloan, 2014) |
| MAM state of the art | Industry reports | (Harris, 2011; Wohlers Associates, 2015) |
| | Government reports | (European Commission, 2014; GAO, 2015; Morris, 2014; NSTC, 2014; PCAST, 2012; STPI, 2013) |
| | Press releases | (GE, 2016, 2015a, 2015b, 2015c, 2014; GE Aviation, 2014; Materialise, 2015; Staff, 2015, 2014a, 2014b) |
| | Technical documents | (Horn and Harrysson, 2012; Jahn et al., 2015; Kranz et al., 2015; Manfredi et al., 2013; Seifi et al., 2016; Laureijs et al., 2016) |

with increasing levels of criticality have been and are expected to continue to be introduced: In 2015, GE certified the first MAM replacement part, a cobalt-chrome sensor housing to retrofit about 400 engines (GE, 2015a). In the end of 2015, GE also started the certification of a new fuel nozzle for their new LEAP engine (GE, 2016). Each engine will contain 19 of these nozzles, and the MAM design presents many advantages when compared to the older version: it builds as a single piece what used to be a subassembly of more than 20 parts; it reduces the weight by 25%, has a five-fold increased durability; and production costs are 30% lower (Morris, 2014). In the near future, GE also plans to substitute low pressure turbine blades with new MAM titanium aluminide blades which are 50% lighter (Wohlers Associates, 2015). Ground testing of the new GE9X engine with those blades has already started (GE, 2015b), and this engine is expected to enter into service in 2018 with the new Boeing 777X (GE, 2015c). The failure of a turbine blade would be more harmful consequences than the failure of a single fuel nozzle, which again would be more harmful than the failure of a case that houses a sensor. While each of these parts are the result of more than a decade of intense research and development activities (Morris, 2014), they introduce new risks due to the uncertainty surrounding MAM parts in terms of real in-flight performance (learning by using).

In the case of aviation, some technical failures can have catastrophic[4] consequences. These catastrophes often shape the way organization (firms and regulators) work (March et al., 1991), and their occurrence can halt use of and progress in a technology indefinitely (Dreshfield and Gray, 1984). Aviation authorities have the difficult task of certifying that MAM parts are safe under conditions of high uncertainty. The possibility of catastrophic failures is of even greater concern in an industry where "learning by using" is required in order to know the real performance of a new product (Mowery and Rosenberg, 1981; RAND, 1992). In the 1950s, the first jet-powered commercial airliner, the De Havilland Comet, suffered several fatal accidents only after thousands of flight-hours, due to the unexpected propagation of fatigue cracks along the corners of the Comet's square shaped windows (Withey, 1997). Demand for aircraft parts made with powder metallurgy grew rapidly in the 70s, but then stalled after the accident of an F-18 combat aircraft in 1980 was traced back to a material failure in its turbine disk which was made using powder metallurgy (Dreshfield and Gray, 1984). In 2013, Boeing 787 s around the world were grounded due to a failure in their lithium-Ion batteries which caused several fire incidents (NTSB, 2013).[5] Regulators incentives are such that they seek to avoid any fatal accidents. As Ralph Keeney, a world leading authority in risk analysis in policymaking, has said: "we cannot banish life-threatening risks, but we can and should learn better ways to deal with them" (Keeney, 1995).

#### 4.1.1. *Sources of uncertainty in MAM*

When compared with other process-sensitive technologies, several characteristics of MAM result in higher variability and make its regulation particularly challenging.

In a stable manufacturing process, contamination is often traced back to a particular batch. For example, imagine the machine's chamber wasn't correctly closed in a particular batch, and so contaminants were introduced into the parts just in that batch, reducing their strength. This problem may have been limited to a single batch, or may have occurred for a series of batches. There is typically no way to know until the problem is identified. In a less mature process, such as is the current state of MAM, lack of process control can mean that each new batch can have different processing parameters, and thus different part outcomes. Thus, the potential for cross-batch variability is higher than for stable processes.

Given current part and chamber sizes, batch sizes in MAM are also much smaller than in semiconductors or pharmaceuticals. To produce a certain number of parts with a small batch size, requires running more batches than in a process with a larger batch size. Each time you run a machine, there is the potential for some aspect of the production environment or process to change (cross-batch variability). Build parameters in MAM are tightly coupled, and, at least, with the current state of the technology, one cannot simply change one of them "ceteris paribus" and achieve a predictable behavior. Changing the part geometry or the part's position inside the MAM manufacturing chamber can affect its microstructure, and thus its performance and safety. In addition, MAM machines have "smart algorithms" which optimize some of the process parameters according to the input. When changing batch size, the design used as an input changes, and revised build parameters are chosen by the machine. Further, if you change the batch size − building, for example, in one batch four parts at a time instead of two − you change the heat transfer conditions inside the machine (heat transfer across unmelted powder is different than across the solid part or across air) and thus change the boundary conditions under which the material is solidified.

High process variability requires additional testing to ensure part quality. Manufacturers do not want to test 100% of the components

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[4] The FAA defines catastrophic as "Failure conditions that are expected to result in multiple fatalities of the occupants, or incapacitation or fatal injury to a flight crewmember normally with the loss of the airplane" (AC 23.1309-1E, 2011).

[5] Not every accident is caused by a regulatory failure, and not every regulatory failure causes an accident. One could argue that the Comet had an accident due to a lack of knowledge, while the case of a Lithium-Ion batteries is one where some steps in the manufacturing process were inconsistent with industry practices, and where "Boeing's and the FAA's oversight of suppliers manufacturing the 787 power conversion subsystem components could have been more effective" (NTSB, 2013).

they make because testing adds cost to the production process: doing a lot of testing can add significant expense (Laureijs et al., 2016). Manufacturers seek only to test enough parts to be sufficiently certain that the parts' required performance specifications are upheld, given the cost (i.e., consequences) of the part not meeting performance specifications. In a stable manufacturing process, obtaining sufficient certainty might involve testing one part per batch or even one part per thousand batches. In immature process cases like MAM, lack of process control can make the cost/benefit tradeoff be that it is important to test one part per batch or even multiple parts per batch to have sufficient certainty that parts are meeting performance specifications. Because batches in MAM are very small, a requirement to test one part per batch requires testing more parts than if there were larger batches. When drug manufacturers make pills, their batches are of thousands or tens of thousands. Therefore, taking out several dozen pills to test the whole batch represents, proportionally, a much smaller fraction of total output than in the case of AM. If the batch size is eight, then testing even just one component per batch means that 12.5% of all parts must be tested.

To understand the variability described above, it is important to understand the sources of uncertainty in the MAM manufacturing process. The MAM manufacturing process involves three broad sources of uncertainty: material source and properties, the process of making the part with the MAM machine, and post-processing of the part (Jahn et al., 2015; Seifi et al., 2016).

For material source, there are three different types of MAM processes − wire-fed, powder-fed and powder bed, each of which requires that the material be supplied in a different form, and requires a different set of parameters to be monitored (Horn and Harrysson, 2012). Within a single process, characteristics of the source material can vary widely depending on the material supplier. Morphology − such as the diameter of the powder particles for powder-fed systems, base material composition and the use of additives to improve materials, all vary with supplier capabilities, and affect the quality of the final part (Manfredi et al., 2013).

Options for the MAM machines using these material sources also vary widely and are based on different fundamental principles. For example, the heat source used to melt the material can be either a laser (Direct Metal Laser Sintering, Direct Metal Deposition), an electron beam (Electron Beam Melting) or a plasma arc (Plasma Deposition), each of which use different physical processes and thus have different requirements (e.g., manufacturing atmosphere, release of residual stresses, etc.) for the MAM build and post-processing steps (Horn and Harrysson, 2012). Within a single MAM approach the total number of input parameters which affect the final product, and therefore which need to be controlled to reduce variability, is more than 150 (Materialise, 2015; *Workshop*, 2015). This variability causes difficulties in establishing robust process control procedures. Building the same part in different locations in the chamber or with different orientations can lead to different results (Kranz et al., 2015). Indeed, as with semiconductors 50 years ago (Lécuyer, 2006), running the same design with the same parameters on the same MAM machine still often leads to different final results (Interviews 1,2,3).

After the part is built with the MAM machine, the part must typically go through several post-processing steps. These may include a thermomechanical treatment to reduce porosity and remove residual stresses; fine machining to adjust part tolerances; or surface treatment to improve resistance to fatigue or corrosion. Similar post-processing steps applied to parts coming out of different build machines can lead to different mechanical properties (Jahn et al., 2015).

### 4.2. Structure of aviation regulation

The situation described in 4.1 poses challenges for the regulatory system as governed by the Federal Aviation Administration. In addition, recent analysis suggests, the FAA has increasingly constrained resources and is suffering an increasing workload caused by greater introduction of new technologies (GAO, 2013).

As we learned through our interviews and archival work, determination of the airworthiness of new technologies for commercial aviation involves a complex, iterative back-and-forth between the FAA and industry (Interviews 4,5,6,7,8), which constitutes an example of management-based regulation. Building upon a generic technology-neutral Code of Federal Regulation, orders are written by FAA officials with input from industry to provide the specific procedures necessary to comply with regulation (Interviews 6,9). In contrast to orders, advisory materials are not compulsory, but developed by the FAA and industry representatives to support interpretation in the context of specific technologies, and to reduce uncertainty that might otherwise increase the cost of compliance for both regulators and firms (Interview 6). Finally, certificates are provided based on FAA officials' assessment that compliance has been achieved (Interview 10). This dialogue between the FAA and industry is facilitated by two types of officers: Organization Designation Authorization, or ODAs, in OEMs and spare part manufacturers[6] are employees of the OEMs designated by the FAA to act as their liaisons. Manufacturing inspection officers are employed by the FAA, and go to all types of factories to confirm whether products comply[7] (Interviews 6,7).

The Federal Aviation Regulations, found under Title 14 of the U.S. Code of Federal Regulations (CFR), govern the certification of new products for commercial aviation (Interviews 1,6). These rules, while hard to change, are subject to interpretation. For example, they say "Each new aircraft fabrication method must be substantiated by a test program" (14 CFR 25.605 b), but they do not describe the requirements of that test program. The regulatory code is supplemented by orders, which are compulsory. For example, order 8120.22 (2013) provides guidance related to the "evaluation and approval of production activities of manufacturers and their suppliers" (8120.22, 2013). Accidents or certification experiences can result in new rules (Code and orders) to make the certification process more efficient and address a safety issue that was missed in the past (Interviews 5,11).

Federal Aviation Administration chief scientific and technical advisors and senior technical specialists provide recommendations for how to achieve compliance with the Federal Code in specific technological circumstances through advisory material (Interview 6). This advisory material is "adaptive," as it is revised periodically according to the needs of the industry, and is easier to change than the CFR. The writing of this advisory material is guided by ODAs in OEMs, and also the manufacturing inspection officers who go to the factory and check whether products comply (Interview 6). This type of advisory material has a role similar to technology-based regulation. Although the applicant for a certificate is free to suggest an alternative method, following the methods described in advisory material can offer significant time and cost savings in achieving certification (Interviews 6,12). The draft (2014) of the still unapproved Advisory Circular (AC) 20.613, for instance, provides applicants with a list of handbooks which contain values of mechanical properties that have already been approved by the FAA, so that applicants do not need to perform additional mechanical testing to prove that those materials are safe.

To show compliance with the regulations, a product must undergo three consecutive certifications: Type Certificate, Production Certificate, and Airworthiness Certificate (See Fig. 1).

A Type Certificate (TC), or design approval, certifies the

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[6] Some small companies have not reached ODA status and are served by FAA consultants called designated engineering representatives (DERs).

[7] Although we focus on the United States and FAA regulation, there are international working groups and bilateral agreements to ensure that regulation and advisory materials written by other aviation authorities like the European Aviation Safety Agency are harmonized. In some cases, like Brazil, regulation and advisory materials are exact copies of those in the U.S. Interpretation will vary with the officers in each country. This said, we expect lessons learned from the FAA to be applicable to other regions like Canada, Europe, Japan and Brazil.

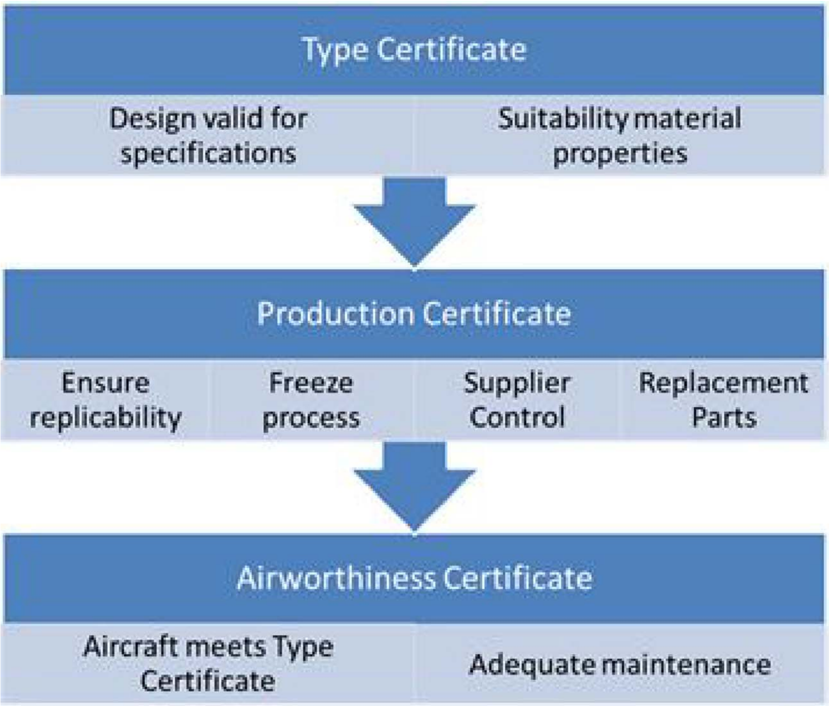

**Fig. 1.** Three different FAA certificates are needed to fly an aircraft.

airworthiness of a given design. To obtain a TC, materials' durability must be empirically proven and meet approved material specifications to guarantee the properties assumed in the designs (14C.F.R. § 25.603, 25.613). Companies need not perform extensive testing for well-known materials. In the draft of the AC 20.613, which is written to replace the outdated AC 25.613-1, the FAA recognizes external sources of material properties which designers can use as a reference. For process-sensitive materials like composite materials, and for MAM in the foreseeable future, the applicant must go through an 'equivalency sampling exercise' to prove that they can replicate the properties (performance) in such databases. Alternatively, applicants may use nonstandard materials like the ones used in and created by using MAM but, in that case, abundant testing is needed to statistically support the mechanical properties being claimed.[8] Creating such datasets may require up to 10,000 test samples for structural parts, a major cost driver in the introduction of new materials (RAND, 2001). As with any performance-based approach, it is challenging to define specifications in the presence of uncertainty: decision-makers typically respond to this uncertainty by employing safety factors, which translates into weight penalties and higher costs (RAND, 2001).

A Production Certificate certifies that the applicant has established a robust quality system and supplier control to ensure the replicability of the properties, which appear in the TC. Once production approval is granted, the manufacturing process is "frozen" under configuration control, meaning that any change made to the process must be approved by FAA (14C.F.R. § 21.150). For MAM, this implies that a manufacturer with a machine certified to produce a certain part would not be allowed to produce a different part without recertifying that machine for both the previous part and the new part (Interviews 1,2,13). This lack of flexibility affects the economic viability of MAM for the production of parts at low volumes, precisely where MAM might be more competitive against traditional manufacturing techniques (Bonnín Roca et al., 2015).

Finally, the Airworthiness Certificate is "FAA's official authorization allowing for the operation… valid as long as the aircraft meets its approved type design, is in a condition for safe operation and maintenance…" (FAA, 2009b). This certificate is "transferred with the aircraft" (14C.F.R. § 21.179), so the final user is responsible for performing adequate maintenance.

Completing the certification process described above can take years or even a decade. ODAs at OEMs and spare parts manufacturer facilities shepherd firms' acquisition of Type and Production Certificates by acquiring and providing the required data for certification to the Aircraft Certification Office (for Type) and Manufacturing Inspection District Offices (for Production) of the FAA. Separately, Aircraft Certification Officers and Manufacturing Inspection Officers make regular visits to factories to confirm that products comply. Inspectors from the Flight Standards organization check that maintenance procedures required to maintain an Airworthiness Certificate are continually upheld by the organization operating the aircraft, and that pre-approved maintenance organizations are used to conduct that maintenance.

### *4.3. Aeronautics industry structure, incentives and oversight*

Although regulation is the same for every company in the industry, different actors have different capabilities, market strategies, profitability and relationships with FAA regulators, and as a consequence very different incentives.

#### *4.3.1. OEMs*

OEMs in the commercial aviation industry can be divided into two categories: jet engine manufacturers, and "airframers" (airframe manufacturers and assemblers).

Three major manufacturers supply jet engines for commercial aircraft: GE Aviation, Rolls Royce and United Technologies. Each is part of a large diversified industrial group; so their interest extends beyond aeronautics. MAM is very appealing to this constituency because engines have thousands of small parts with complex geometries, which are expensive to manufacture using traditional manufacturing techniques. In addition, jet engine manufacturers have a longstanding tradition of high-performance alloy development for engine blades, and this expertise is a core competitive advantage. Jet engine manufacturers have chosen to develop MAM competencies in-house (Interviews

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[8] The amount of data needed is statistically determined in what are called "A-Basis" and "B-Basis" values, depending on the application. An A-Basis value, for example, is defined as the value at which "at least 99% of population equals or exceeds value with 95% confidence or the specification minimum when it is lower" (Jackson, 2007).

3,4,14), including acquiring existing MAM part production companies. For instance, to bring the knowledge in-house and avoid undesired competition, GE acquired two different MAM companies, Morris Technologies and Avio Aero, which have enabled it to produce its fuel nozzles and the titanium low pressure turbine blades, respectively (Wohlers Associates, 2015).

The market for large commercial aircraft is a duopoly formed by Boeing and Airbus (Nolan, 2012). For smaller aircraft, two other manufacturers, Embraer and Bombardier, hold about three quarters of the market (Nolan, 2012). Commercial aircraft manufacturers are companies focused only on the aerospace industry. In addition, in the last decades they have become "integrators" of increasingly complex aircraft sections manufactured by their Tier-1 suppliers (Slayton and Spinardi, 2015). For instance, Boeing only performed about a third of the total production activities for their 787 model. The manufacture of critical parts of the airframe such as wings, wingtips, several fuselage sections and horizontal stabilizers were outsourced to domestic (e.g., Spirit, Vought) and foreign companies (e.g., Alenia, Mitsubishi, Kawasaki) (Horng, 2006; Tang et al., 2009). Thus, although they have internal R & D programs in MAM, they would like to have a pool of MAM suppliers from which they could choose and diversify their production (Interviews 15,16,17).

Interestingly, while regulation is almost the same for both engines and airframes, there are differences in some of the regulatory requirements as well as the regulators themselves, which have both technological and organizational roots (Interviews 6,8,18). Both products have a different level of criticality: while the failure of a single engine is not necessarily critical because there is another engine on board,[9] airframe failures have a high probability of having fatal consequences. From an organizational perspective, not only are the manufacturing companies and their business strategies different, the officials writing the rules for aircraft and engines are also different, and are located in entirely different Directorates within the Federal Aviation Administration. Thus, different "traditions" (regulatory methods and customs based on historical precedents) have organically grown within different Directorates (Interview 8). An example of these differences is "Casting Factors" (14C.F.R. § 25.621). Casting Factors are safety factors which the FAA requires manufacturers to employ in addition to designers' safety factors to account for the increased variability in the mechanical properties of castings, compared to wrought or forged metals. Casting Factors must be applied to airframe components made with casting but not to engine components. Given the lower criticality of engine parts, the cost that additional safety factors would impose in terms of weight penalties would arguably be greater than the reduction in risk (Khaled, 2014). Castings are used widely today in engine components. Since the 1980s airframe industry members have claimed that casting technology has evolved enough to control variability and that the use of casting factors could be dropped (Eylon et al., 1983; Torrey et al., 1989). However, casting factors remain in the regulation relevant to airframers (14C.F.R. § 25.621) and have become an example of regulatory lock-in.

OEMs have daily interaction with the FAA, and when they introduce a novel design, they discuss with the FAA the procedure required to achieve compliance (Interview 6). The interaction between FAA and manufacturers is a good example of a management-based approach: it happens through designees who have been granted a special Organization Designation Authorization (ODA). Designees are employed by manufacturers. They have the responsibility to communicate with the FAA the details about the manufacturers' activities, serving as a way for the FAA to access manufacturers' tacit knowledge (Downer, 2010). Due to the large knowledge asymmetry between OEMs and the FAA, OEMs have a significant influence over the impressions of the FAA's officials, who end up evaluating "trust" in the people they are certifying rather than technology[10] (Downer, 2010). After the interaction between the OEM's ODA and the FAA, the FAA formally answers the OEM by writing an "Issue Paper" with a proposal for means of compliance (Interviews 6,19). These issue papers are not publicly available to protect the intellectual property of the manufacturer.

One of the greatest fears OEMs have is that "rogue suppliers" (suppliers who implement changes to their production process without the consent of the OEMs) could start making MAM parts without the required knowledge and statistical substantiation of quality (Workshop, 2015). This is a matter of both public safety and competitive advantage: OEMs know that an early failure of an MAM part could severely slow or even for a period halt the commercial adoption of the technology in which they have invested heavily (Interview 4). Therefore, they have incentives to create some degree of public knowledge, and they have expressed their willingness to share aspects of their data which are not core to their competitive advantage (*Workshop*, 2015).

### 4.3.2. *Suppliers*

OEMs have a wide variety of suppliers. However, we would expect MAM to be attractive to companies like "machine shops" which manufacture the type of products which can be substituted by MAM, and to MAM manufacturers which currently do not supply to the industry but would like to expand their business. Becoming a supplier for the aeronautics industry is not easy, given the many barriers to entry, like high capital requirements and complex certification requirements (Pearce, 2013). In addition, profit margins have decreased over the last decades due to strategic sourcing (Rossetti and Choi, 2005). However, being able to occupy a niche like MAM in the market would likely increase suppliers' bargaining power and profitability.

Suppliers are an increasingly important part of the industry, given that airframers have substantially increased the number and complexity of outsourced content in the latest generation of their aircraft (Slayton and Spinardi, 2015). While some of these suppliers are in the U.S., many are located abroad and serve as a mechanism for OEMs to enter foreign markets (FAA, 2008). One example is Japan, where Boeing's suppliers have in the last half century developed capabilities, such as composite materials manufacturing, which may be higher than Boeing's (MacPherson and Pritchard, 2007).

Suppliers are FAA-certified through the OEMs, to whom they give the minimal amount of information about their product, and they generally do not have communication with the FAA (Interviews 7,20,21). In cases where suppliers have higher capabilities than OEMs, issues related to knowledge asymmetry could also appear. The concentration seen among the "system integrators" in aerospace is also apparent among the OEMs, and among their suppliers (Nolan, 2012). These suppliers are specialists, with unique capabilities, and regulating them to ensure safety is a challenge for OEMs, and ultimately for the regulator. To help OEMs in the supplier selection process, institutions like the Performance Review Institute, a cooperative industry effort which groups OEMs and suppliers, develops "checklists" which serve as a basis to accredit suppliers (PRI, 2016). However, our conversations suggest that, although there is an industry-wide interest in developing such checklists for MAM because of a growing interest among suppliers, balance has to be found between the amount of proprietary information that firms are willing to share compared to the information that is necessary for a complete and thorough checklist (Interview 17).

In the U.S., FAA performs Supplier Control Audits (SCA) to randomly chosen high-tier suppliers (Order 8120.23, 2013). Results from past SCAs conducted at Boeing, where 40% of its audited suppliers had at least 1 nonconformance, suggest that unsatisfying manufacturing

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[9] As Downer (2011b) points out redundancy is not always a good criteria because some events may affect all engines at the same time. For example, in 2009, an airplane had to land on the Hudson river after multiple bird strikes caused both engines to fail (Downer, 2011b).

[10] Nevertheless, our interactions with industry, civil and military suggest that OEMs have internal employees with safety requirements which are much more stringent than FAA's.

practices do arise (Simons, 2007). The lack of oversight of suppliers is an increasingly important problem due to the increased subcontracting in the industry, where airframers have started outsourcing not only small parts but important sections of their aircraft to Tier 1 suppliers, which might be located abroad (Slayton and Spinardi, 2015). The oversight of the increasing number of foreign suppliers make it even harder for the regulators, who see how their resources diminish. An audit to the FAA supplier audit procedures states:

> "*We acknowledge that it is not FAA's responsibility to provide oversight of manufacturers' suppliers. However, in our view, it is counterintuitive to decrease the number of supplier audits that FAA performs when use of suppliers has steadily increased and FAA has consistently determined that supplier oversight is a problem*" (FAA, 2008).

The opacity of the relationships across the supply chain creates additional problems to ensure safety. For instance, the B787 was the first airliner to use lithium-ion batteries, but those batteries were not manufactured by Boeing but by Yuasa, a Japanese manufacturer. The electrical system was designed by Thales, a European company, which subcontracted the battery components to Yuasa. In 2013, after two severe incidents involving batteries catching fire, the FAA decided to ground all B787 s worldwide (Ostrower et al., 2013). In 2013, after the investigation of one of these fire incidents, the National Transportation Security Board (NTSB) released a report stating:

> "*FAA's oversight of Boeing, Boeing's oversight of Thales, and Thales' oversight of GS Yuasa did not ensure that the cell manufacturing process was consistent with established industry practices*" (NTSB, 2013).

The same document further reports "insufficient guidance for manufacturers… in determining and justifying key assumptions in safety assessments" and "Insufficient guidance for FAA certification engineers to use during the type certification process to ensure compliance with applicable requirements" (NTSB, 2013).

Summing up: taking into account the recent evolution of the industry, the increased complexity of the supply chain, the lack of communication with regulators and the increased complexity of the subsystems they produce, suppliers may become a more important source of risk than OEMs.

#### 4.3.3. Spare parts manufacturers

The aftermarket constitutes the most lucrative business in aeronautics: engine companies may sell the engine below cost and make their profit in the aftermarket (Hollinger and Powley, 2015). In 2016, Boeing forbad Spirit Aerosystems to sell spare parts directly and obliged Spirit to sell them through Boeing, as part of an ambitious plan of tripling the sales of their business in parts and services (Ostrower, 2016). For this business segment, MAM is very attractive because it allows companies to reduce inventory costs and the need for additional equipment (Holmström et al., 2010).

Spare parts can be fabricated either by the OEM, or by third party suppliers that need to obtain a Parts Manufacturers Approval (PMA), which "is a combined design and production approval for modification and replacement articles. It allows a manufacturer to produce and sell these articles for installation on type certificated products" (FAA, 2013). If predictions that MAM will eventually dominate aftermarket sales prove true,[11] PMA holders who do not invest in MAM risk losing a significant share of their business. However, a 2015 survey suggests that aftermarket suppliers lack the capital availability and innovative culture to introduce new technologies (Spafford et al., 2015).

OEMs claim that some of these third-party suppliers may constitute an additional source of risk, as PMA holders and FAA designees who certify them, often lack enough knowledge to develop safe replacement parts (FAA, 2009a). The argument is that a PMA, although they may produce a part which has the same geometry and looks the same as a part manufactured by the OEM, have not gone through the same statistical performance substantiation. On the other side, PMA holders claim that their products offer substantial cost savings with respect to the components sold by OEMs, and are safe and that their business viability is being hurt by having to go through a mandatory FAA review and approval for each specific part (Doll, 2015; FAA, 2009a).

An FAA Commission was established in 2007 to resolve this dispute. In 2009, a report was released stating that TC holders − that is, the OEMs − had not always been objective in their statements, and that the major driver of the debate was economic (FAA, 2009a). Related to this point, in March 2016, IATA, representing the airlines, officially joined a European Commission investigation by filing a complaint against OEMs for abuse of dominant market position in the spare parts market (IATA, 2016).

Independent of the business case, the level of complexity and technological knowledge required to manufacture aircraft parts continues to increase, as more and more safety-critical parts are considered for MAM. As long as these concerns are not properly addressed, risks derived from inappropriate spare parts may also rise. Arguing for greater FAA involvement in the regulation of PMA holders, one FAA official writes, *"Aftermarket suppliers do not generally have the same* ***resources or talent pools*** *available to OEMs"* (Khaled, 2015).

Due to the lack of financial resources and human capital, spare parts manufacturers might be able to handle technological uncertainty less effectively than OEMs, thus becoming a more relevant source of risk.

#### 4.3.4. Summary

In Section 4.3, we categorize the players in the aeronautics industry into OEMs, suppliers and spare part manufacturers. Each type of player has different market incentives, technical knowledge, financial resources and a different level of regulatory oversight. Table 2 contains a summary of our findings.

Differences across players also create differences in the ability of different players to abate technological risks. Risks coming from MAM's technological uncertainty might be higher outside the OEMs. Therefore, regulation must balance innovation and safety, and accommodate the differences across the diverse range of stakeholders.

We turn now to a discussion of some of the solutions proposed to minimize risks posed by MAM.

### 4.4. Solutions being considered to safely introduce MAM in commercial aviation

At the moment of writing, FAA has not written any regulation for MAM, but FAA has been communicating with firms about the best way to tackle MAM's challenges and there are already some solutions being considered (Interviews 4,8,18). These solutions were also discussed during workshop we organized, operating with Chatham House Rules as a neutral party with industry and government leaders. First, under a scenario in which no additional action is taken by the FAA, OEMs would individually certify their suppliers and spare part manufacturers to ensure they comply with their manufacturer requirements (Interviews 4,14). Second, currently manufacturers are over-engineering their MAM parts, voluntarily increasing their factors of safety to account for technological uncertainty (Interview 4). The use of safety factors could also be mandated by the FAA, as they were in the case of Casting Factors (Interview 15). Third, public resources could be used to create shared material specifications (such as process or performance specifications), which could be directly used in the FAA certification process (Interviews 1,2,22). This has successfully been done with composite materials, where the creation of a public database at Wichita State University allowed for a decrease of an order of magnitude in certification cost, and more than two years the certification time (Tomblin et al., 2002). Companies that have invested significant R & D

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[11] The technical community doesn't yet know how changes in raw materials over time may affect the mechanical properties of future MAM spare parts

**Table 2**
Different players in the aeronautics industry have different incentives and levels of resources to tackle technical challenges.

| | Engines OEMs | Airframe OEMs | Suppliers | Spare parts manufacturers |
|---|---|---|---|---|
| Profitability | Low in new products, high in spares | Low in new products, high in spares | High for niche applications, low otherwise | High |
| Regulatory Oversight | Direct and continuous | Direct and continuous | Rare, indirect through OEMs | Direct, but not continuous |
| Technical capabilities | High | High, but some core competences outsourced | Depending on the application, higher or lower than OEM | Lowest |
| Financial resources | High | High | Constrained | Lowest |
| Incentives | Keep MAM in-house<br>Increase barriers to entry<br>Gain aftermarket | Have multiple MAM suppliers<br>Gain aftermarket | Occupy niche<br>Gain bargaining power | Reduce inventory<br>Reduce equipment costs |
| Concerns | An early accident could abruptly stop the introduction of MAM | An early accident could abruptly stop the introduction of MAM | OEMs not helping develop industry-wide guidelines | Losing market share to OEMs if not investing in new technology |

resources in being at the technological frontier will have little incentive to share knowledge core to their competitive advantage (Interviews 4,16,17). That said, technological leaders may have incentives to share second or third generation knowledge, to increase supply chain capabilities, increase competition among their suppliers and thereby reduce costs (*Workshop*, 2015). They may also have incentives to share such knowledge to reduce the risk of other companies' failures hurting the public image of, or regulatory friendliness to, MAM and thereby preventing the front-runner from being able to use a technology in which they are heavily invested. In both the second and third cases, care would need to be taken to update regulations and material specifications to match the latest in technological capabilities. While "technology-forcing" regulation can accelerate technology development towards a currently unattainable policy goal (e.g., Gerard and Lave, 2005; Lee et al., 2010); overly prescriptive regulation can create a disincentive to explore newer, better, and (at least initially) riskier technologies.

## 5. Discussion

### 5.1. *Regulating an emerging technology, given varying capabilities across the supply chain*

Regulators (in the case of aviation, the FAA) of emerging technologies are faced with balancing increasingly stringent safety requirements, risks associated with technological uncertainty, and opportunities for innovation, which could bring extended social benefits (Mandel, 2009). Technology-based, performance-based, and management based regulation each have advantages and disadvantages with respect to these trade-offs (e.g., Coglianese and Lazer, 2003; Gilad, 2010); while adaptive regulation (e.g., Wilson et al., 2008; Mandel, 2009) offers a series of policy mechanisms to balance technology uncertainty and the need for innovation, independent of regulatory style. However, both literatures fall short when addressing challenges classic to emerging technologies. Such challenges include needed links between the characteristics of a technology (such as technology maturity and sources of uncertainty) and the type of regulation, and differences in technological knowledge and capability across players in the same industry.

Developing performance-based regulation for immature technologies is challenging due to the lack of reliable physical models, of clear specifications when there is uncertainty around which parameters matter, and of control in manufacturing (Coglianese et al., 2003; Notarianni, 2000). Proponents of management-based approaches argue that firms normally have more knowledge about their technology than regulators (Coglianese and Lazer, 2003). However, not all firms in the same industry necessarily have the same knowledge, no less the same capabilities: In our case of MAM in aviation, while some companies have more knowledge than the FAA, others have less. Regulators obtain their knowledge directly from trailblazers. At the same time, suppliers have economic incentives to implement the technology but do not have the financial resources and human capital to internally develop the same level of knowledge as the leading companies. These suppliers might benefit from technology-based approaches, which provide specific guidance on how to reliably produce proven technologies. In the case of suppliers, the reduction in incentives for innovation associated with technology-based regulation may be of less concern, since they are unlikely to be focused on innovation, given their resources. Thus, the reduction in incentives to innovate in this case might easily be outweighed by a reduction in the technological risk. Focusing on a restricted set of technologies, if matched with requirements to share data, also could increase available process and performance data to help improve understanding and reduce uncertainty with respect to the technology. Finally, technology-based approaches could potentially decrease the risks derived from an inadequate oversight of suppliers by the OEMs.

We propose a typology in which, given the risk preferences of the regulator, the regulatory approach could depend on the level of technological uncertainty at each firm across the supply chain, and which evolves over time (Fig. 3). Our framework is an example of what McCray et al. (2010) called "Planned Adaptation", a regulatory system which is revised when knowledge is improved, and which takes proactive action to produce such knowledge (McCray et al., 2010; Petersen and Bloemen, 2015; Wilson et al., 2008). Coming back to the concepts of "Art" and "Science" introduced by Bohn (2005), we define a state, "Craft", which corresponds to an intermediate stage in the learning process where there have been important advances in terms of replicability, but the scientific understanding is still limited (Fig. 2). The regulatory approach (given the risk preference of a particular regulator) would then depend on the stage of the learning process that firms are in (Fig. 3).

Under this framework, technology-based approaches are applied to firms whose knowledge is far behind the technological frontier. Meanwhile, leading companies who have developed in-house knowledge which is well ahead of their competitors, would benefit from management-based mechanisms. This would give manufacturers at the technological frontier the opportunity to implement the technology in more critical applications while transferring their knowledge to the regulators, which could use this new information to adapt existing regulation (Fig. 4).

Once a technology is sufficiently mature, its performance predictable, and adequate standards developed, the system would transition to a performance-based approach where any player could take advantage of the full potential of the technology.

To avoid situations of "regulatory lock-in," regulations should also be established with the mechanisms to ensure transition from one approach to the next. One possible mechanism is the establishment of sunset clauses to ensure the periodic revision of the regulation (Posner and Vermeule, 2003; Sunstein, 2013; Wilson et al., 2008). In this case, one challenge might be establishing a revision frequency short enough to accommodate rapid changes in technology, but long enough for industry to assimilate the regulatory changes. A second mechanism could

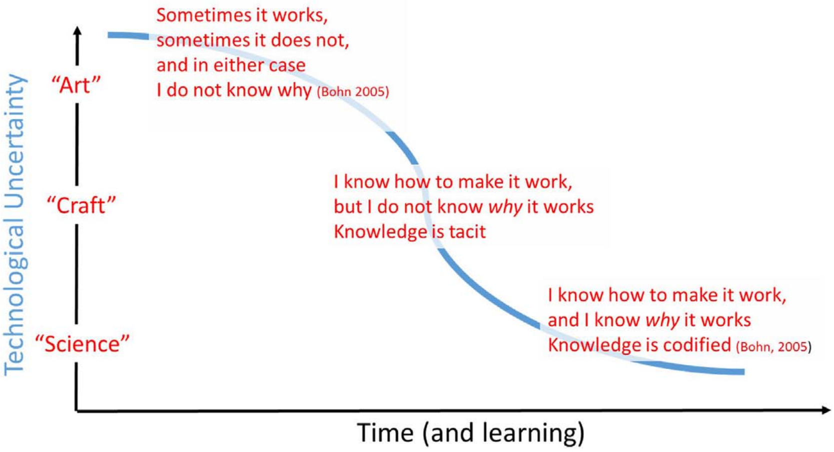

**Fig. 2.** Graphical representation of the evolution of technological uncertainty, and the correspondence with the concepts of "Art," "Craft," and "Science".

be the creation of a formal review process through which single firms could prove to regulators that they have mastered the technology enough to go beyond the pre-approved applications. In aviation, this would mean extending FAA's direct oversight to those suppliers specialized in MAM. Such a review process would increase the opportunities for innovation in the industry, but creating the guidelines for a public review process while the technology is still highly uncertain and information is held as proprietary within leading OEMs would likely be difficult.

One strategy to bypass this hurdle would be to increase the discretion of the certification officers employed by the FAA, the street-level bureaucrats. These certification officers possess more knowledge than they are allowed (and perhaps even able) to codify in formal guidelines due to their interaction with the OEMs around proprietary information, and could perform informal reviews of suppliers to assess their capabilities compared to the industry leaders. They also have contextual knowledge specific to each company, which can be instrumental in identifying how best to implement the spirit of the Code and Orders in the context of the organization. Notably street-level bureaucrats might be incentivized to adopt the most conservative posture and maintain the status quo, since a failure could jeopardize their career and have significant economic consequences. At the same time, the risk of capture could also increase, the career paths of certification officers are often such that they come from industry and might go back to consulting to industry or industry itself (Johnson, 1983).

Increased discretion still requires checks and balances. Organizational culture can be controlled through selection and training of the street-level bureaucrats (Hill, 2003; Piore and Schrank, 2008). Management can augment coherence across cases, and exert a greater influence over the organizational process, by dividing firms into comparable categories, where the type of problems and the ways of solving them are similar (Piore and Schrank, 2008). Creating mechanisms for FAA agents and companies regulating suppliers to compare interpretation of regulation within the context of OEMs, suppliers, and aftermarket suppliers independently, could help toward this end. Finally, generation of publicly available scientific data to inform the review process, similar to what was done with composite materials; and increased certification office discretion, are likely instrumental to minimizing the risks of regulatory capture, as well as to eventual technology maturity and use by all. In addition to providing factual information, this publically available scientific data also serves as a form of 'popular participation' (Piore and Schrank, 2008) or "tripartism" (Ayres and Braithwaite, 1995). To aid the broader advance of the technology, the publicly available scientific data need not come from the latest generation of products still instrumental to corporate competitive advantage.

Although there are strong market pressures to develop MAM, research shows that it can take decades before new materials and process technologies are well-codified, well-understood scientifically, and thus mature (Bohn, 2005; NSTC, 2014). The evolution of advanced composite materials, in which levels of federal investment were much higher than MAM (Bonnín Roca et al., Forthcoming), serves as an example. Despite being first introduced in aviation in 1950s (RAND, 1992), a Boeing executive suggested that today, more than sixty years later, composites are still insufficiently well understood by the aeronautics industry, resulting in suboptimal designs (Sloan, 2014). The prospect of such long, or even longer, development times, is yet another incentive to develop adaptive regulation with discretion in implementation.

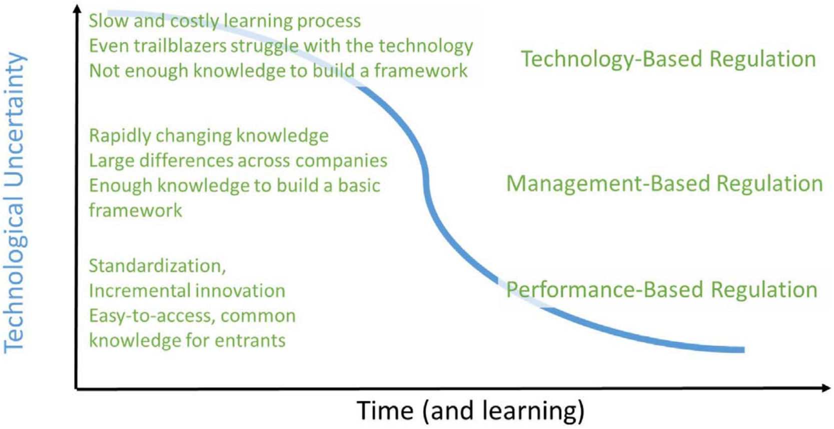

**Fig. 3.** The risk-benefit trade-offs of Technology-, Management-, or Performance-Based regulation depends on the level of technological uncertainty.

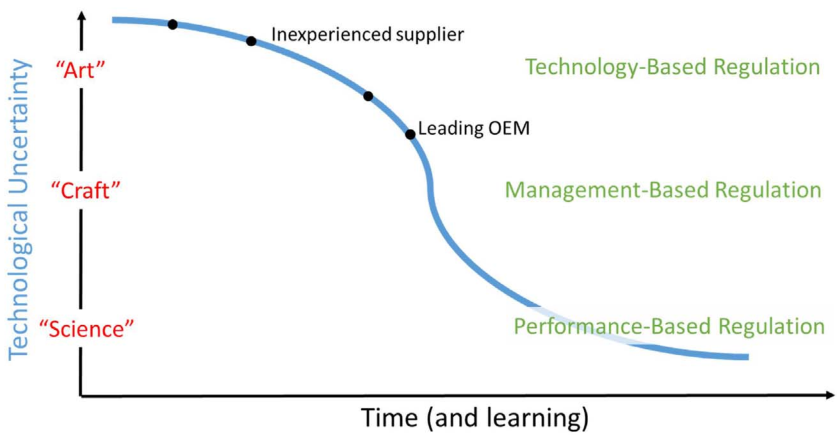

**Fig. 4.** Interpretation of difference of knowledge across players for the current state of MAM.

### 5.2. Lessons from MAM for regulating emerging technologies in other industries

Theory-building seeks "to guide and inspire new ideas, not to validate existing ideas" (Hargadon and Sutton, 1997).[12] Based on the knowledge gained from our extreme case of MAM in civil aviation, we propose a framework to guide both further refining of our theory in other industrial contexts as well as eventual theory-testing with Table 3 and Fig. 5.[13]

To help contrast MAM with other manufacturing technologies, we leverage existing literature to highlight differences in sources of uncertainty and in learning mechanisms across industries in Table 3. We use bicycle assembly as an example of a component assembly-focused (in contrast to process-based) manufacturing activity. In Table 3, the number of constituents represents the number of unique components in a product. The number of constituents for pharmaceuticals is low, as pharmaceuticals are composed of only a handful of active ingredients (Ma'ayan et al., 2007). In contrast, the number of constituents in genetic engineering is high, due to the need for accurate positioning of nucleotides in extensive DNA strings (Mullis et al., 1986). While the development of semiconductors required new testing techniques (Lécuyer, 2006) − as does MAM (Mani et al., 2015), pharmaceuticals benefit from generic quality control procedures developed for other types of chemicals (Gowen et al., 2008). Semiconductor microchips can be tested during intermediate steps of their production, like the wafer testing performed before the wafer is cut (Zant, 2014), and the manufacturing process of pharmaceuticals can be tested and controlled during production via spectroscopy (Blanco et al., 1999). Conversely, in other manufacturing processes like MAM or genetic engineering (Li et al., 2015), testing can be challenging or impossible mid-process, and is mainly performed at the end of the process. Even when testing can be done at the end of the process, it's not always true that all performance can be predicted by those tests. Performance of semiconductors can to a large extent be measured and thus tested once fully assembled (Zant, 2014). Thus, learning by using is comparatively low. In contrast, pharmaceuticals can have unpredicted side effects on certain patients even after they are approved for commercialization, due to differences across the population (Wood et al., 2003), therefore learning by using is high.

Some of the above-described differences arise from the differing levels of maturity of the industries we are comparing. For example, semiconductor devices are today testable at intermediate stages, and do not need much learning by using. Neither of these was true when semiconductor manufacturing was at a level of maturity comparable to MAM today (Lécuyer, 2006). As a technology matures, e.g., evolves "from art to science," there is an evolution in the sources of uncertainty and learning mechanisms. With increasing levels of maturity, learning by using generally has decreasing returns, the need for new testing techniques decreases, and new ways to test the product in intermediate stages emerge.

The extreme case of MAM in civil aviation provides important insights for the regulation of immature process-based technologies. MAM in civil aviation is a more constrained case than many technologies in other contexts in its level of safety requirements, level of technological uncertainty − including the extraordinary number of variables, challenges in testability, and requiring learning by using, and variety of capabilities in its players. In Fig. 5 below, we identify three constraints for which MAM is extreme: industry structure (number of firms in the industry given vertical disaggregation and competitive dynamics), safety implications for human life, and contributors to technological uncertainty, and then show where various emerging technologies are on those spectrums in particular industrial applications. Here, the industry structure and safety dimensions will vary with industrial application, while the contributors to technology uncertainty will vary with the technology itself. By looking at the extreme case of MAM for commercial aviation, we are able to shed insights into how regulatory approaches can differ when each of the constraints are removed. The comparison across technologies in Table 3 helps build our framework insofar as it provides comparative measures for the type and number of uncertainty sources in a particular industry, and the increased impact on human safety and well-being in sectors where learning by using plays a more important role.

The top category in Fig. 5 is industry structure, and depends on the number and variety of firms and the level of vertical disaggregation. We combine the variety of firms and level of vertical disaggregation into this single measure due to the correlation between the vertical disaggregation of an industry and the number of opportunities for uncertainty to be introduced in the final product. Vertically integrated firms have fewer suppliers than horizontally integrated firms, and therefore the sources of uncertainty arising from firm heterogeneity are reduced. In addition, the larger the number of firms in an industry, the more difficult it is for the regulators to oversee all of them.[14] For

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[12] In the words of Hargadon and Sutton (1997), "The extent to which our model generalizes to other industries and technologies can only be determined by hypothesis-testing research in large, representative samples of other organizations involved" in the regulation of emerging technologies.

[13] Here, by hypothesis-testing research we intend to refer to research that, in contrast to our paper, sets up natural experiments that generate data that is amenable to the use of standard econometrics methods for the evaluation of the impact of certain types of regulations in safety (e.g., number of incidents/accidents) and innovation (e.g., patents).

[14] To locate an industry along the first axis, one option for regulators might be to use an index such as the HHI (Rhoades, 1993), which quantify the level of integration of an industry as a function of the number of firms N and the market share of each firm $s_i$ ($HHI = \sum_{i=1}^{N} s_i^2$). A limitation of this measure include the relatively large value when one of the firms has a very large market share, when compared to a market where each player

**Table 3**
Different manufacturing processes have different sources of uncertainty and learning mechanisms which shape the optimal regulatory approach.

| | Genetic Engineering | Pharmaceuticals | Semiconductors | MAM | Bicycle assembly |
|---|---|---|---|---|---|
| Number of constituents | High | Low | High | High | Low |
| New measurement techniques required | Yes | No | Yes | Yes | No |
| Testability during intermediate phases of production | Not yet | Yes | Yes | Not yet | Yes |
| Learning by using | High | High | Low | High | Low |

**Table 4**
Summary of participant observations in this paper.

| Type of participant observations | Number of hours |
|---|---|
| America Makes Project Management Review | 35 |
| America Makes monthly Powder Bed Webinar | 10 |
| Workshop in Washington, DC with 25 leaders from industry and government | 10 |
| Visits to manufacturers and workshop in the aeronautical cluster of Sao José dos Campos, Brazil | 15 |
| Interaction with Department of Mechanical Engineering at Carnegie Mellon University | 5 |
| Nadcap meeting, Pittsburgh 2015 | 5 |
| Total | 80 |

**Table 5**
Interviews conducted.

| Organization | Position |
|---|---|
| OEM 1 | Senior Manager, Metals |
| OEM 2 | Head, Manufacturing |
| OEM 2 | Type Certificate |
| OEM 3 | Engineer, Additive Manufacturing |
| OEM 3 | Leader, Additive Manufacturing |
| OEM 4 | Director, Manufacturing |
| OEM 4 | Head, Additive Manufacturing |
| OEM 5 | Lead, Additive Manufacturing |
| OEM 6 | Technical Manager |
| OEM 7 | Director, Manufacturing |
| OEM 8 | Manager, Airworthiness |
| OEM 8 | Director, Regulation |
| Supplier 1 | Director, Additive Manufacturing |
| Supplier 2 | Director, Additive Manufacturing |
| Supplier 3 | Director |
| Supplier 4 | Managing Director |
| Supplier 5 | Plant Manager |
| Supplier 6 | Manager, Additive Manufacturing |
| MAM Equipment supplier | Business Development Manager |
| Research Center 1 | Director, Materials Testing |
| Research Center 1 | Associate Director, Materials Laboratory |
| Aviation Regulator 1 | Additive Manufacturing Team |
| Aviation Regulator 1 | Additive Manufacturing Team |
| Aviation Regulator 1 | Additive Manufacturing Team |
| Aviation Regulator 1 | Advanced Composite Materials |
| Aviation Regulator 1 | Retired |
| Aviation Regulator 1 | Retired |
| Aviation Regulator 2 | Additive Manufacturing Team |
| Aviation Regulator 3 | Director, Aircraft Certification |
| Aviation Regulator 3 | Team Lead, Aircraft Safety |
| Public Body 1 | Additive Manufacturing Team |
| Public Body 2 | Chairman, Additive Manufacturing |
| Public Body 3 | Team Lead, Structural Materials |
| Public Body 4 | Project Leader, Additive Manufacturing |
| Public Body 5 | Senior Technology Manager |
| Public Body 6 | Assistant Director, Advanced Materials |
| Public Body 7 | Chair, Materials & Manufacturing |

instance, the pharmaceutical industry faces similar challenges to MAM in terms of safety requirements and uncertain performance, but R & D activities are concentrated in a much smaller pool of large companies (Comanor and Scherer, 2013). Managing this concentrated pool of large players requires fewer resources, and thus common management-based regulation may be sufficient.[15]

The second category in Fig. 5 is safety implications for human life. This category combines the number of lives endangered by a single accident, and the ease for meeting desired safety levels without negatively affecting the expected technical performance. For instance, the automotive industry is a highly regulated industry, for which in the last decades many responsibilities have been transferred from the OEMs to small suppliers (Whitford, 2005). However, an accident in aviation incurs a much larger loss in terms of human lives than a car accident. Furthermore, in automobiles the weight gain caused by using a higher safety factor has a much lower impact on performance than in aviation, the latter for which additional mass translates into a more immediate and even greater increase in operating costs due to increased fuel consumption. As such, using MAM in automotive entails lower risks than in aviation and fewer performance trade-offs, which may allow for an earlier transition to performance-based regulation. Safety levels used by regulators could be used to locate an industry along the axis for the second category. For instance, Starr (1969) compares technologies estimating the probability of an accident per person-hour of exposure. Similarly, the goal set by FAA is 1E-9 catastrophic accidents per operational hour (FAA, 2000).

The third category in Fig. 5 is the relative magnitude of technological uncertainty. This category aggregates the effects of technological complexity, difficulties in testing a product during and after its manufacturing process, and needs for 'learning by using.' Emerging biotechnology fields like synthetic biology are more similar to MAM in terms of variety of player capability because lowered barriers of entry have allowed the entry of players which are much smaller than it would be expected for an emerging technology (Oye, 2012). However, in contrast to synthetic biology, MAM suffers from additional within-part variability. In MAM, some sections may not melt perfectly, resulting in almost undetectable defects. Further, in MAM the effect of the particular engineer configuring and overseeing the equipment might be higher than synthetic biology, which may increase the need for street-level bureaucrat discretion (regardless of whether a technology, management, or performance-based approach is taken).

One option for policymakers to assess uncertainty in emerging technologies could be expert elicitation, but results are subject to overconfidence and in general do not take into account variables which go beyond well-established knowledge (Morgan, 2014). In industries where accidents are rare, regulators may also collect information about past microevents and near-misses which can be used to prevent future

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(*footnote continued*)
has the same share. Another measure might be the number of steps along the supply chain from raw material to final product. More work would need to be done to find the ideal measure.

[15] We do not include firm-level heterogeneity as an axis in Fig. 5, because in our framework firm-level heterogeneity is primarily relevant for management-based regulation (not technology-based or performance-based regulation). While firm-level heterogeneity could be taken into account in technology-based (different firms could have different technology implementation requirements) or performance-based regulations (different companies could have different performance requirements), within a single country such regulatory differences are rare. (In contrast, for example, to different regulatory requirements across developed versus developing countries such as agreed upon in the Montreal Protocol (Velders et al., 2007).

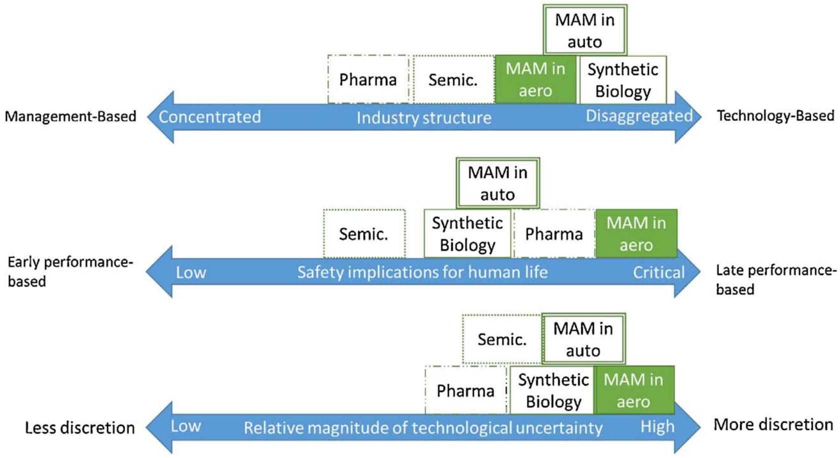

**Fig. 5.** The appropriate regulatory approach, which depends on the structure of the industry, its safety implications and the relative magnitude of technological uncertainty, varies with technology and industrial context.

accidents (March et al., 1991). The participation of regulators in industry events and standard-setting committees may also accelerate the transfer of knowledge about technology change. In any exercise seeking to collect quantitative measures, we suggest using the different dimensions in Table 3 as a typology for thinking about sources of uncertainty in emerging technologies, and thus informing the data collection. Given that uncertainty has not only the "known unknowns" but also the "unknown unknowns" (Morgan et al., 1992), any estimation of the uncertainty will be incomplete.

The regulatory approach that has the most promise to balance safety and innovation depends on technology and industrial context, and requires combining all three dimensions of Fig. 5.

Our typology suggests that current FAA certification procedures might not be well suited to achieving public safety goals, due to the differences in knowledge, resources and regulatory oversight across industry members, and the high sources of uncertainty in the case of MAM. To balance safety and innovation in the case of MAM in civil aviation, our typology suggests 1) an early technology-based regulation for suppliers not under direct FAA oversight, 2) delaying transition to performance-based standards until further technology maturity to avoid catastrophic accidents early-on prior to industry acceptance of the emerging technology, and 3) increasing regulatory discretion of designees and certification officers given the high sources of technological uncertainty.

However, policymakers may have reasons to move out of this balance point. For instance, in safety-sensitive industries like pharmaceuticals and aeronautics, where the accidental loss of human lives can have a large impact, regulators may want to be even more risk averse (Fischhoff et al., 1978). In that case, they will likely want to reduce regulatory discretion and create technology-based regulation such as the use of special safety factors, or the creation of material databases as discussed in Section 4.4. Unfortunately, removing these safety factors may be very difficult once greater knowledge has obviated their need. The specific policy ultimately depends on the product being regulated, even within the same industry. For instance, in civil aviation, sensor housings are less safety critical than turbine blades. Likewise if we look at the pharmaceutical industry, safety factors can be applied to some products like antibiotics or cosmetics, but not to others like cancer treatments.[16] Conversely, for some regulators the promotion of innovation might weigh more than the safety concerns. In that case, regulators might choose to refrain from using technology-based standards and move towards performance standards relatively early, letting industry experiment the best ways to reach the regulatory goals.

Our typology, as with any model, is a simplification of reality and should only be viewed as a tool to think about the problem at hand: here regulation of emerging technologies to balance innovation and safety. Further metric development and theory testing would be necessary to propose precise measures. While our work focuses on process-based manufacturing technologies, lessons from our case of MAM in civil aviation for the regulation of emerging technologies might also be useful for "traditional" industries such as banking, which are undergoing large changes due to the emergence of technologies such as virtual currencies or blockchain.

## 6. Conclusion

Our work uses the extreme case of an immature technology with high technological uncertainty in a safety-critical industry − MAM in civil aviation − to shed light into how the characteristics of a technology and its industry structure should be taken into account in regulatory design. Our contributions to the literature are twofold: First, we suggest that not all immature technologies should be regulated in the same way, because the sources of uncertainty behind these technologies can be different. Second, past literature on risk regulation has treated industry members as homogenous, ignoring the variation in firms' underlying motivations and technology capabilities, and the changes in both of these over time. Our findings suggest sources of uncertainty across industry players come not only from differences in knowledge and technological capabilities, but also differences in their financial interests, business traditions, position in the supply chain, and regulatory oversight. Given this situation, technology-based regulation, which has traditionally been reviled as an innovation-constraining approach, could serve as a useful tool both to control risks and to enhance the gathering of knowledge. Such knowledge gathering is essential in technologies where certain aspects of performance can only be discovered through use (and thus a marked "learning by using" component.) Possible interventions to address the variety in capabilities in an emerging technology across an industry and change therein over time include creation of adaptive regulation mechanisms such as sunset clauses, the establishment of formal case-by-case review processes, and an increase in street-level bureaucrats' discretion.

Our findings, by focusing on the extreme case of MAM in civil aviation, offer important insights for how regulation may need to differ with technology and industrial context. It also offers important, specific, insights for regulation in other immature, process-based technologies such as synthetic biology, semiconductors, and chemicals, and other market applications with high safety standards such as automotive and pharmaceuticals. To this end, we first present a framework for thinking about sources of uncertainty across different technology contexts. We conclude with a typology for how regulatory configuration could take into account industry structure (number of firms), performance and safety requirements, and the relative magnitude of technological uncertainty.

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[16] We thank one of our anonymous reviewers for this example.

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[17] Due to the sensitive nature of our conversations, we want to avoid revealing the identities of our sources