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Precaution and Evidence - Legal Systems as Context Factors of Engineering Innovation and Entrepreneurship

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1. Introduction

Engineering innovation and technology entrepreneurship—whether by a single founder establishing a new venture or a multidisciplinary team within a large industrial firm—are embedded in cultural, legal, and physical contexts that constrain, facilitate, and otherwise influence the innovation process.

Within any entrepreneurial context, assessing and managing risks are high priorities. When it comes to environmental hazards and other threats to health and human safety, we face the challenges of optimizing potential benefits while minimizing possible negative outcomes and making a profit—a formidable task, indeed. In the case of potentially catastrophic or avoidable risk, we may find that a particular product or system should *not* be developed or implemented because the potential negative outcomes are disastrous or irreversible.

The situation is even further complicated by uncertainty and its inverse relationship to investment and commitment: discerning risk requires time and resources, and firms are resistant to abandoning products after they have made a significant investment. In other words, by the time we have conclusive evidence about the risks associated with an innovative sociotechnical system, we may find our capacity for constructive action greatly diminished.

Managing these contextual factors in engineering innovation and technology entrepreneurship is difficult enough in a single polity (economic/political/social/cultural system) and is even more difficult when we are working across multiple polities, whether the innovation is being undertaken in multinational corporations, non-governmental organizations (NGOs), or the "small and medium-size enterprises (SMEs), which are the main engines of job creation and innovation on both sides of the Atlantic." (U.S.-EU Joint Report on T-TIP Progress to Date, January 2017, n.p.)

It took many years to arrive at the understanding of contextual factors in engineering innovation and entrepreneurship that is outlined above. This understanding is not universally shared on either side of the Atlantic, nor does it play an active part in the thinking of all segments of the population in either case; it is, however, both a product and an expression of a pervasive shift in Western values and culture (common to the U.S. and EU). This paper provides a historical perspective on this pervasive cultural shift and the key events that contributed to it and explores its significance for the regulatory systems that are most relevant to engineering innovation and entrepreneurship.

To focus our analysis, we consider the issues raised by and explored in the negotiations associated with the Transatlantic Trade and Investment Partnership (TTIP). Our study began as an examination of the factors that contributed to a need to modify engineering curricula. What we ended up with is more a history of an important cultural shift combined with a case study in the complexities of determining how differences in legal and regulatory systems relate to differences in values and preferences, specifically with reference to the U.S. and EU and the ways these polities view precaution versus evidence in the management of technology-related risks.

The next section of this paper provides an introduction to the TTIP as a case study in the problem our work addresses: understanding legal systems as context factors of engineering innovation and entrepreneurship. Section 3 provides a historical perspective on the shift in values that culminated in the PP. Section 4 identifies a few of the most important social innovations and bodies of research that emerged in response to the changing awareness of the nature and ethical significance of technology-related risks—and that can be used in the education of engineering innovators and technology entrepreneurs. Finally, we discuss the potential for strengthening both the EU and U.S. systems through cross-cultural collaboration in the form of achieving regulatory coherence.

2. The Transatlantic Trade and Investment Partnership (TTIP) as Case Study

The European Union (EU) and the United States (U.S.) have been attempting to create a free trade agreement since the 1990s (Fung 2014: 445). The latest attempt at such an agreement is the Transatlantic Trade and Investment Partnership (TTIP), also known as the Transatlantic Free Trade Area (TAFTA), which the EU and US began negotiating in 2013. The TTIP offers potential economic growth benefits on the order of GDP increase of 92-162 billion USD for the EU and 68-129 billion USD for the U.S. (Fung 2014: 446). One of the major challenges associated with the TTIP is achieving "regulatory coherence," that is, a reconciliation of U.S. and EU health and safety standards. The European Commission estimates the effects of eliminating the barriers as follows: "Studies suggest that between two thirds and four fifths of the gains from a future agreement would come from cutting red tape and having more coordination between regulators." (EU Commission 2013: 2)

These potential gains notwithstanding, "the domestic regulatory schemes and polices of both entities create formidable obstacles to successful negotiations." (Fung, 2014: 448) In Europe, NGOs, political scientists, and citizens see more risks than opportunities in achieving regulatory coherence. (see Felbermeyr et al. 2016) At risk especially are European social and environmental achievements. The standard characterization of the differences is that the EU regulatory regime is based on the precautionary principle (PP). Faced with uncertainty about possible risks, the idea is to proceed with caution unless there is conclusive evidence that no risk exists or there is a reasonable way to handle the risks, for example, the kinds of safety management procedures required in the European REACh Regulation, which governs the manufacture and use of chemicals. The EU system thus gives high priority to non-economic concerns. In contrast, the U.S. regulatory regime is based on cost-benefit analysis (CBA) and gives priority to economic, quantifiable factors. In most domains, regulation is triggered in the U.S. only after conclusive evidence of harm exists.

The two approaches are not, upon close examination, diametrically opposed. Along with several scholars and government officials, we will argue that the perspectives can be reconciled. Nevertheless, the attempt at reconciliation highlights differences in priorities that interact with innovation processes. Because it gives a higher priority to non-economic and non-technical values in the first place, the PP influences the way firms develop new products and what is seen as safe or environmental friendly enough in the process of innovation. The recognition of differing values and the expectations of customers become important aspects of product development and of engineering work in the early stages of a project.

Regardless of whether a TTIP partnership is ever actually established, the research and analysis that have been produced in connection with those negotiations are relevant for understanding the challenges of establishing technology assessment and risk management systems that function effectively across polities. One of the most interesting implications of this literature is that the most important differences between the EU and U.S systems lie in assumptions, priorities, and existing regulatory regimes, rather than in standards, goals, or values. Both the EU and the U.S. have expressed firm commitments to achieving coherence *without* lowering of standards (Die Bundesregierung 2016: 8). Statements from the Office of the U.S. Trade Representative assert that the EU and U.S. share higher standards with comparison to other members of the partnership.

As mentioned above, the standard characterization of the difference between EU and U.S approaches is that they diametrically oppose each other, especially where food and safety regulations are concerned. For example, as a precautionary measure, the EU prohibits importation of genetically modified produce and bans the use of phthalates (a carcinogen) in the manufacture of children's toys. In contrast, genetically modified products are used extensively in the United States and assumed to be substantially the same as conventionally produced products. The U.S. EPA recognizes the risk posed by phthalates, but conclusive evidence of significant harm would be required to trigger regulatory action regarding them.

The differences, however, may not be as stark as they are often presumed to be. U.S. Trade Representative Michael Froman (2013) warns that viewing the two systems as diametrically opposed tends to oversimplify the ways the precautionary principle and cost benefit analysis are implemented in the EU and the U.S. Case studies comparing risk-reducing decisions in the two polities suggest "treatment of risk is approximately the same, and the perception of highly disparate regulatory effects may be caused by more heavily publicized risks." (Morrall 2011: 452) Other studies have suggested that "the regulatory principles may not be fundamentally irreconcilable. Instead, *the ways they are implemented* may be a major cause of regulatory divergence." (emphasis added) (Fung 2014: 452)

We began with a mental model of the differences between the U.S. and the EU that assumed divergence based on differences in history and culture, as depicted in figure 1 below. After we conducted detailed analysis of the evolution of attitudes toward technology-based risk and the way those attitudes are reflected in regulatory and educational systems, we modified the model as depicted in figure 2 below.

Fig 1: Our original divergent model of differences between the U.S. and EU

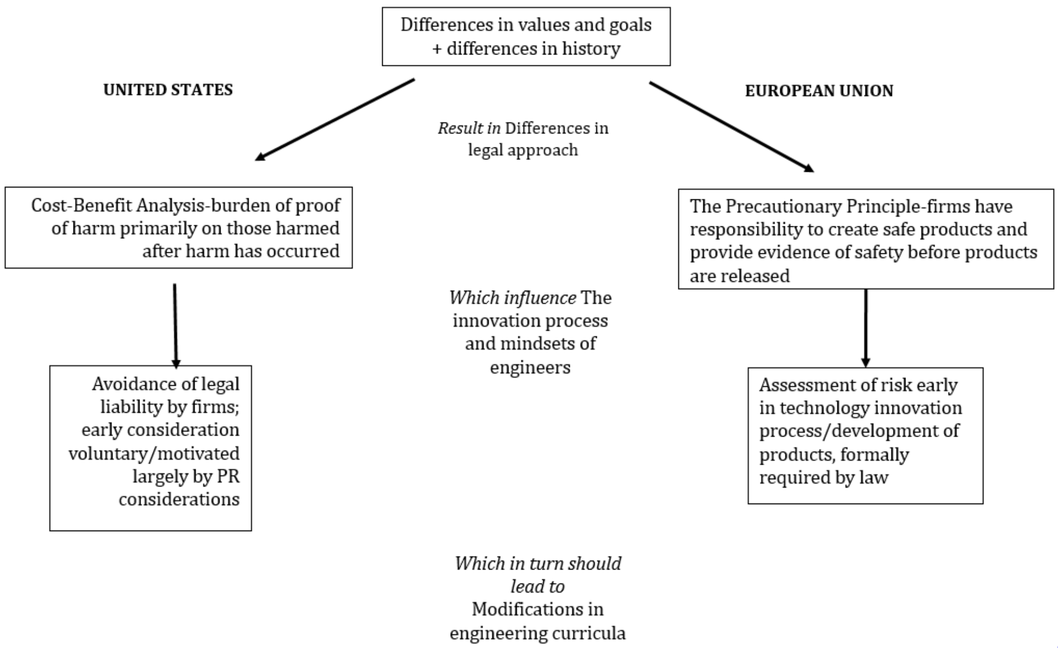
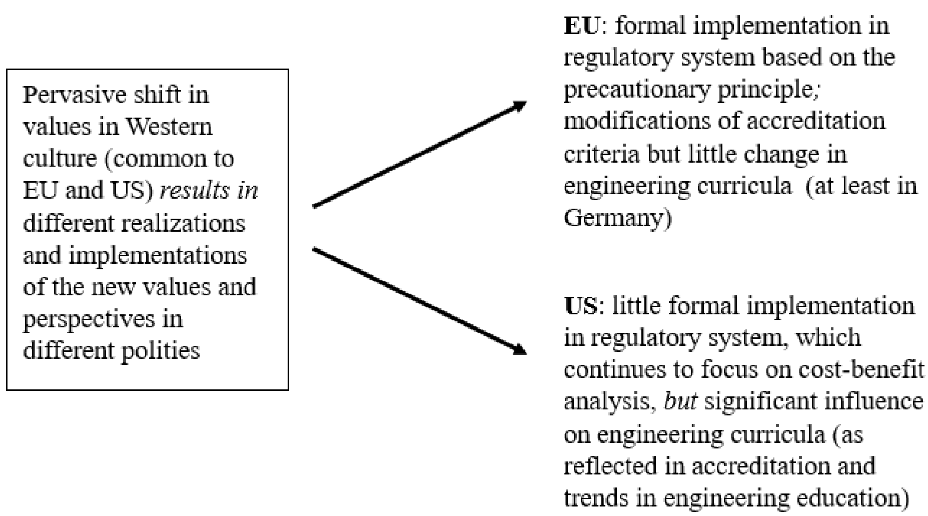


Fig. 2. Our revised model of differences between the EU and U.S.



Specifically, it appears that the EU regulatory system has been more affected by this cultural shift than have its engineering curricula, at least in Germany. Conversely, it appears that the American engineering education system has been more affected by this cultural shift than has its regulatory system. For example, the EU has implemented the precautionary principle in a number of regulations, and it is a part of the general treaty among the states that form the EU (Art 174). The U.S. regulatory system continues to focus on cost-benefit analysis, but the perspectives and attitudes of precaution are embedded in engineering education through the

EC2000 accreditation criteria, specifically, the requirement to consider and integrate environmental and other non-technical considerations into the major design project.

These differences in regulatory schemes have significant implications for engineering education. In a situation whether either the state (regulatory agency) or individual consumer (plaintiff in law suit) has to produce evidence of safety or harm, it is difficult to provide causal proof that specific instances of environmental or health damage are caused by a specific product, substance, or activity of a particular firm. Beyond a cost-benefit analysis, which is typically rather superficial, the firm is relatively safe and has little responsibility for considering environmental and health risks.

In a system based on the PP, the product development process faces the responsibility for demonstrating that possible negative side effects do not exist or can be reasonably managed. Firms are deterred from introducing products to the market because providing proof of long-term safety is expensive and time-consuming. Firms operating outside of the PP approach consider possible risks and damage—negative headlines and breaking news can ruin the firm's reputation; however, the PP provides some incentives to deal with more alacrity with the possibilities of negative effects. Providing evidence of harmlessness becomes a normal responsibility if firms want to make money. Customers reasonably ask for a safe product. The obligation of the firm is to provide safe products and to *show* that those products are safe.

Although there have been numerous criticisms of the precautionary principle, it is generally viewed as the most highly developed framework for dealing with unknown risks and uncertainty. In the end, a cost-benefit analysis is part of the PP. Firms have to calculate whether it is worth the money to undertake intense scrutiny of possible side effects. The difference is the valence we give to sales and employment opportunity, or to health and the environment. In the next section, we trace the process by which we arrived at the PP.

3. From "Breaking Eggs" to "Better Safe Than Sorry": A Historical Perspective on Coping with the Undesirable Effects of Technology

The historical narrative that follows could be briefly summarized with this claim: Enough broken eggs and we get to the understanding that technology can be shaped by society, that technical solutions respecting health and environmental aspects are not necessarily more expensive than technical solutions that do not respect those values, and that we can do much better than settle for "end of pipe" solutions that focus on dealing with negative outcomes as opposed to limiting or preventing them in the first place. From our current perspective, this new understanding seems rather obvious. Understanding how it came to be should provide useful context for education in engineering entrepreneurship and innovation.

As David Noble demonstrates in *Progress without* People (1995), the negative effects of technologies have been considered since the beginning of industrialization. It took over 50 years to move from thinking about the undesirable effects of technology as inevitably entangled with its beneficial effects to a mode of coping with technologies that is organized according to the principle of "better safe than sorry" (the Precautionary Principle). In brief, the evolution started from the assumption that the good (wealth and better living conditions) is inevitably connected with the bad (pollution and deadly occupational accidents) and the ugly (exploitation of the third world) of technologies. In other words, the good, the bad, and the ugly are distinguishable but inseparable.

We evolved into a view in which we take responsibility, individually and collectively, for long-term environment damage and threats to human health and safety. Furthermore, we now recognize that those most likely to be harmed are also least likely to exert power in the decision-making process, and often also least likely to benefit economically or otherwise from the technological innovation that produced the risk or harm. In intense European discussions about new technology, this uneven allocation of benefits and risks appears unfair and unacceptable.

Although the commonplace that "you can't make an omelet without breaking some eggs" originated during the French Revolution, it was first used in print to frame a discussion of science in July of 1941 in *Scientific Monthly.* (James 1941: 51) The published version of an address, the article was titled "Science and Society," and the author of the article was F. Cyril James, then Principal and Vice-Chancellor of McGill University in Canada. Conflating technological innovation with science, he asks what role science has played in the transformation from the "crystalline organization of medieval society, compact and conservative [to a world that] had been knit together by the developments in transportation and industry, while society showed signs of flying apart and was far from conservative." (James 1941: 51)

Noting that the "apologists of science" are as vehement its critics, he suggests that "We are confronted by a paradox at the outset of our inquiry, and can only proceed if we recognize that the defenders and the critics of science are both accurate, in the light of their basic assumptions." (James 1941: 51) Acknowledging the paradox, however, is not enough because "It is apparent that the impact of science on western society, during the period [1475-1875] has not been a simple one. *Omelettes are not made without breaking eggs, and it may clarify our thinking if we separate the constructive effects from those that have been purely destructive.*" (James 1941: 52)[1]

James concludes, "Looking backwards, therefore, it is apparent that the impact of science on society has not been wholly beneficial. The ethos of western society has not responded to the changes in its material environment, so that today we face a major crisis. But if we are willing to face the major problem of deciding upon our ideals, the forces that science has placed at our disposal are already sufficient to make the attainment of those ideals a practical possibility." (James 1941: 60) James thus frames the problem in a technologically deterministic view in which innovation moves forward inexorably and in the direction of material progress, while society fails to keep up (cultural lag). Getting beyond or outside of this framing has been one of the most challenging aspects of the evolution we describe here.

It is worth noting that James' article appears in the same issue of *Scientific Monthly* in which the entrepreneur and radio and television broadcasting pioneer David Sarnoff published an

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1 We will not stop here to critique the logic underlying this proverb. An insightful analysis is presented by Vuolo (2013)

opinion piece titled “A New World?” in which he asserts that “history may record the most momentous happening in 1940 as having taken place in the laboratory rather on the battlefield. I am thinking that the truly epoch-making event of the year may be man’s first successful attempt to release atomic energy, through the isolation of Uranium 235.” (Sarnoff 1941: 37) In keeping with his reputation as a visionary, Sarnoff projects a utopian scenario:

> With atomic power, people may be able to light, heat, ventilate and refrigerate their homes with ease and at trifling expense. Ships, railway trains, automobiles and airplanes may be fueled for life at the time they are built. Men may carry in their pockets personal radio telephones which will enable them to communicate through the world. A myriad of new products and services will become available to all. Many of the old hardships and deprivations—the sources of social and economic unrest—will disappear. A new society, dwelling in a new economy of abundance, will be born. Is this all a dream? Yes, but it is the dream stuff of science, and our dreamers are the scientists who are opening new vistas for civilization. (Sarnoff 1941: 37)

In this vision, technology leads, culture lags, and nuclear scientists are visionary leaders, quite different from our current understanding, but not without a basis in fact. This technological optimism persisted after World War II ended, sustained by programs like Eisenhower’s “Atoms for Peace” and the “German Economic Miracle.” Improvements in manufacturing led to decreasing prices and economic growth, as well as high rates of employment and increasing net incomes of households. Technological innovation and progress were assumed to be directly correlated, as in General Electric’s tagline “Progress is our most important product.” But there was evidence coming in that these assumptions might not be justified.

A series of events in the 1960s, including the publication of Rachel Carson’s *Silent Spring* (1962), began to undermine the optimism and faith of the 1940s and 1950s. Carson warned of the potentially catastrophic results of unrestrained use of pesticides. The report of the Club of Rome (Meadows *et al.* 1972), titled *The Limits to Growth*, challenged the assumption that growth in GDP was the answer to all development and social problems. That report was largely responsible for initiating public discussion of issues such as global warming, population growth, and energy shortages. The U.S. established the Office of Technology Assessment (OTA) in that same year.

In 1980, the U.S. government, at the request of then president Jimmy Carter, produced the *Global 2000 Report*, a study of the future of the world that drew on all of the available expertise in the federal government to make plans for meeting the challenges of the future. At about the same time, a series of incidents at Three Mile Island (1979), Bhopal (1984), and Chernobyl (1986) revealed that human activities in one place can affect developments in regions of the world that are far away, as when the nuclear cloud of radiation set free at the Ukrainian Chernobyl disaster circled all over Europe. In Europe, the rise of the Green Party in numerous countries and their growing influence on setting the political agenda became evident. (Rüdig 1991)

In 1991 in Germany, the Verein Deutscher Ingenieure (VDI-The Association of German Engineers) published “VDI 3780 - Technology Assessment-Concepts and Foundations.” The substance of this document is discussed in the next section. What is notable here is that the VDI recommendations took the U.S. Office of Technology Assessment as an archetype to be emulated (see Bimber 1996, the development in Germany is described by Bröchler et al.1999). In the U.S., meanwhile, Executive Order 12,866 issued by Bill Clinton, formally established cost-benefit analysis as the formative principle of environmental, health, and safety regulation in the U.S. In 1995, the OTA was closed.

At the same time, however, leaders in engineering education in the U.S. issued a series of reports that called for radical reform in U.S. engineering education. (ABET, 1995; ASEE Engineering Deans Council, 1994; Board on Engineering Education, 1995; Bordogna, Fromm, and Ernest, 1993)[2] Although the primary goal of reform was to eliminate the stultifying effects of “bean counting” accreditation procedures, the larger goal was to prepare graduates for engineering practice by equipping them with contextual (also sometimes called “professional”) skills. These calls for reform resulted in the EC2000 accreditation criteria, which require, among other things, that graduates demonstrate the ability to integrate “realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability” into the design process, including the development of new products. This ability, in turn, rests on other abilities including an ability to function on multidisciplinary teams; an ability to define and solve problems; an understanding of professional and ethical responsibility; an ability to communicate effectively; the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and society context; ability to engage in life-long learning; and a knowledge of contemporary issues.

These changes in engineering education in the U.S. occurred almost simultaneously with German adoption of technology assessment and with the formation of the European Union in 1993 (Maastricht Treaty) and the treaty formalizing regulation by the PP in the Article 191 of the Treaty on the Functioning of the European Union. In Article 130 r, no 2 the Maastricht Treaty puts the PP at the center of initiatives to protect the environment.

As the value system in the west came to place greater emphasis on considering future effects and the rights of competing stakeholders, many of whom have little political or economic power, institutions and regulatory systems evolved, though in different ways. The liability laws in many countries were updated and tightened. The Directive “85/374/EEC - Liability for Defective Products” forced the member states in 1985 to tighten the national regulations. The European Union made another step forward to cope with undesirable effects of technologies by implementing the precautionary principle in a series of legislation focusing on protection of the environment and the consumer. Economic costs and benefits took on a much lower priority or were at least considered equally with various competing values.

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[2] This cluster of reports published in the mid-1990s was followed by another cluster appearing about ten years later, for example, Clough, 2004 and 2005 and Galloway, 2007.

As mentioned earlier, this shift in values needs consideration in engineering education and requires adaptation in curricula. The next section of this paper provides examples of the kinds of content that might be included in engineering curricula to make appropriate adaptations.[3]

4. Specific Content that Might Be Included in Engineering Curricula to Better Prepare Engineers for Socially Responsible and Financially Successful Innovation

Discussions of changing engineering curricula to better prepare engineers tend to focus on two levels of interventions: (a) high-level admonitions to include topics such as sustainability or risk management in the curriculum and (b) examples of specific projects or other educational activities that students could engage in. Although these kinds of interventions definitely have a place in curriculum planning, in our view, they provide either too little or too much direction for engineering educators. In line with this thinking, we have identified two analytical models (the Collingridge Dilemma and the VDI model of competing and dependent values in technology assessment) and exemplars from a body of literature (social science research) that could be included in or otherwise inform engineering curriculum design.

4.1 The Collingridge Dilemma: Understanding Why It Makes Sense to Consider Potential Risks Early in the Technology Development Process

The implementation of formal technology assessment was a major step forward. The work of David Collingridge provides evidence that assessing risks early in technology development is superior not only in principle but also in practicality. In his 1980 book, *The Social Control of Technology*, Collingridge presented what has come to be known as "the Collingridge Dilemma." This dilemma is depicted in the figure below. Especially for radical innovations – facelifts or incremental innovations are not in the focus here – there is an inverse relationship between our knowledge of risks and our range of options for mitigating those risks.

New technologies with potential of harm are typical examples of the Collingridge Dilemma. Key technologies like biotechnology or nano-technology (discussed in detail below) with a wide range of different trajectories (symbolized by the arrows between the boxes indicating the stages of the development process) open various paths for innovation processes connected with varying positive and negative effects.

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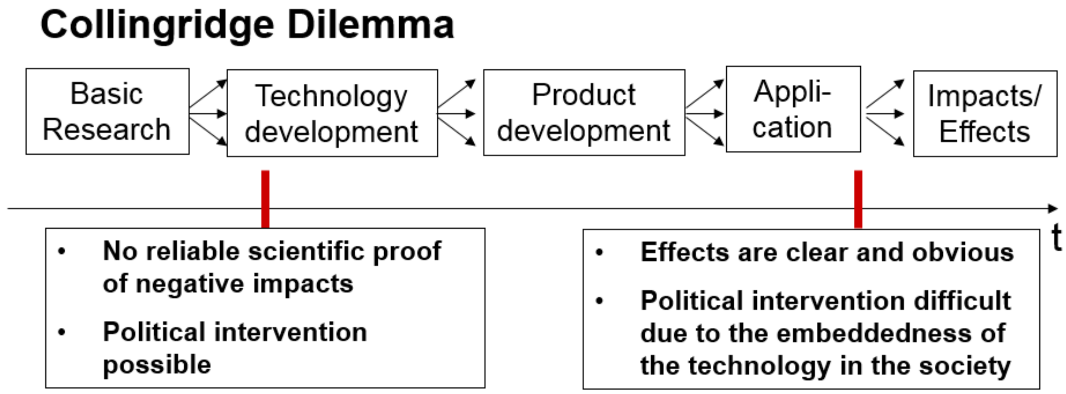
[3] In the conclusion of this paper, we compare the German and American accreditation criteria, which are not all that different from each other. We do, however, see a difference in the way the criteria are implemented in the curricula, with a fuller realization in the U.S.

Fig 3: The Collingridge Dilemma and the Innovation Process



In an early stage of technological development, political actors or other decision-makers lack scientifically proved knowledge to make an informed decision, but the costs of rejecting or abandoning a technology are still low. Firms might lament about postponed, lost, or wasted economic opportunity, but they have not spent a lot of money yet. Therefore, they can cope with a moratorium or a permanent ban on a particular technological development. In later stages, the side effects might be much clearer and more obvious, but firms are less willing to abandon a project because they already spent huge sums of money. It is understandable that they would strenuously object to losing their investment. Thus, later in the process, it is difficult to redirect or stop a technology development process unless there is a catastrophe. The precautionary principle shifts the burden of proof of safety to the producers of a technology or substance, and they must prove that it is safe.

Nano-materials are a good example to give some evidence to the argument. The substances are widely used in cosmetics, household products, and other use-contexts. These materials can be very helpful and offer new material and product characteristics. When reduced to the nano-scale, substances change their physical or chemical qualities, offering chances for product and process innovations. Unfortunately, it is not reasonable to presume that the chemical or physical qualities are the only changing aspects of the material in focus. A lack of knowledge is the result, because an innovator cannot be sure whether a material turns toxic, is carcinogenic, or stays as harmless as it was in the established and formerly used size. Thus, with nano-materials, we face the Collingridge Dilemma. And we still do not have an answer to the question of how to manage risks connected with new products or chemical substances. As David Resnick (2003) points out in an article titled "Is the Precautionary Principle Unscientific?"

> Risk management. . . employs normative assumptions about the types of harms we should be concerned about, the level of risk that is acceptable, as well as the distribution of benefits and harms. If we are concerned about cancer, then we can use risk assessment methods to tell us how many people are likely to develop cancer if we approve a new pesticide. If these methods tell us that one out of every one million people will get cancer, we must decide whether this is an acceptable level of risk; and if not, what to do about it. To answer these sorts of questions in risk

> management, we must appeal to social, political and moral values. (Resnik 2003: 333)

The model provided by Collingridge and Resnik's analysis make it clear that social, political, and moral values should shape the research and design process from the earliest stages. They do not, however, help us understand the ways in which values compete with and depend upon each other in the technology development process.

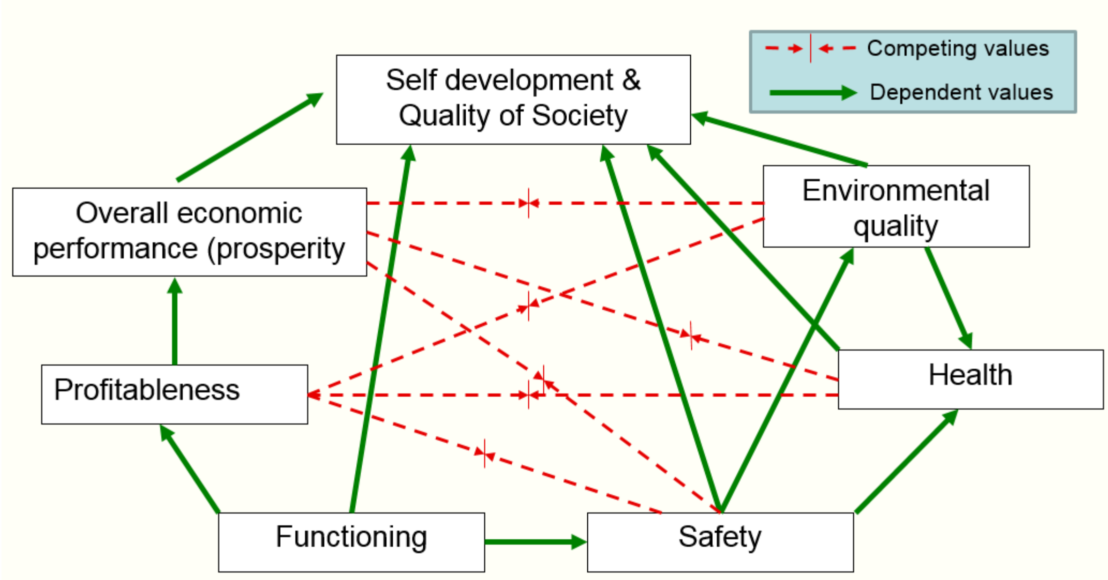
4.2 Understanding the Ways in Which Values Shift, Complete, and Depend on Each Other in Technology Development

Technology assessment is a far from perfect tool, but it is also an attempt to achieve a widely shared goal: to decide on a societal level which technologies to use and which to avoid. As the quote from Resnick above suggests, the assessment and management of risk require that we articulate and establish priorities in our values. For engineering educators, innovators, and practitioners who are accustomed to evaluating new technology using values of efficiency or technical superiority, the transition in values outlined earlier in this paper created significant problems. In Germany, a major contribution in the change process was the "VDI 3780 – Technology Assessment – Concepts and Foundations" (1991). In this report, the Association of German Engineers (mentioned above) offered an "honor code" for engineering work, asking for technological development that considers competing values as legitimate and important.

As a rule-setting body, the VDI was responding to societal demands for more considerate technical and economic development. Although the conceptual framework provided by the VDI had no regulatory force, it did raise awareness and led to an intensified discussion about the pros and cons of technological advancement. It got outside of the conversation in which the positive and negative impacts were seen as inextricably linked and highlighted the responsibility of firms and their engineers for side effects of innovations. In the explanatory parts of the text, the VDI argues that technical developments have to consider more than just the economic and technical aspects of a project. In practice, this meant shifting focus from the values on the left side of the diagram below and embracing all of the values as well as recognizing the relationships among the values.

The VDI 3780 transferred responsibility for the side effects to the innovating firms. Not answered is the question how to cope with this new task: Will firms set up technology assessment departments with specialists to check for the negative impacts? This would duplicate one of the problems of the formal TA approaches. In the general discussions, we see usually two groups of scientific counterparts: Those who are in favor of a technology stressing the positive aspects and rejecting the negative effects and the critics who stress the importance of health, safety and the environment. A lot of examples are given in the case studies in the publication *Late Lessons from Early Warnings* (Gee *et al.* 2001) and the second volume (Harremoës *et al*. 2013). To avoid negative impacts, the developmental and the assessment processes have to be reconciled: Only a hand-in-hand process appears promising to come to innovations that respect the validity a wide array of (competing) values.

Fig 4. Competing and dependent values in the process of technology assessment (VDI-regulation 3780: Technology Assessment – Concepts and Foundations)



4.3 The Value of Social Science Research for Understanding Context Factors

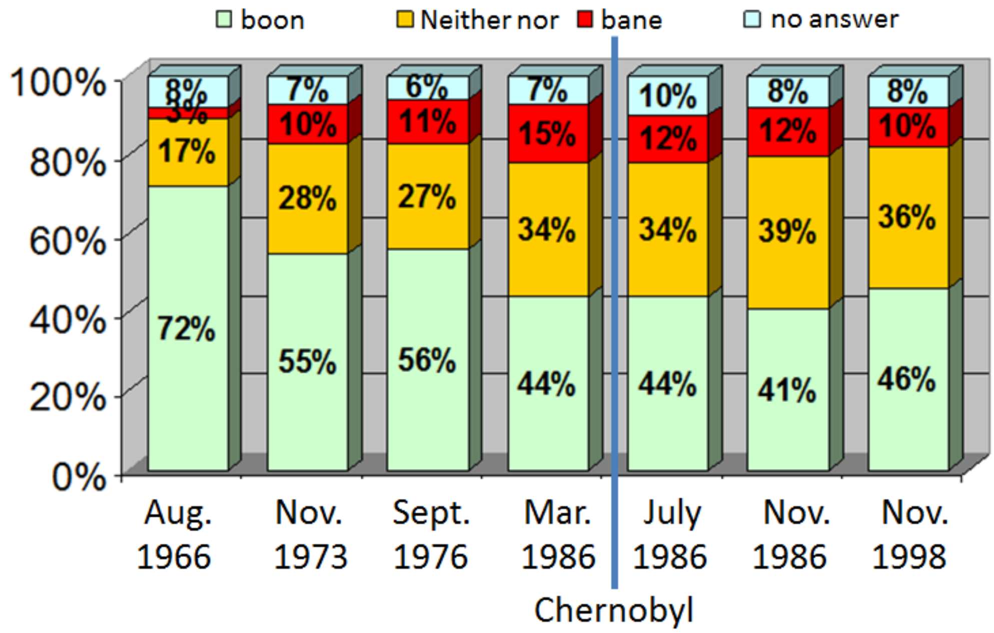
The values shown in Figure 4 reflect the increasing importance of values and expectations of consumers and citizens. This implies a need to consider a wider range of aspects of developing technologies and a better understanding of the stakeholder groups and social processes that influence values and expectations. Fortunately, there is a large body of social science research that provides input to the technology development process. Here we discuss just a few relevant examples of that research.

Results of research done by social scientists reveal a general change of values: the concern for health issues and the environment was no longer just part of a weird or peculiar green lifestyle. The SINUS Institute[4] analyzed for years the changing milieus in Germany (Sociovision 2010). Milieus are a means to describe segmentations of society that are not purely made up by strata based on income, status, education, or power resources. Milieus reflect the way of living, the expectations, the things we do in our leisure time (go gambling, to the movies or to an art gallery) or how we like to be entertained. During the 1980s a separate and distinct alternative or green milieu was identifiable (Vester *et al.* 2001). In the 1990s green values or concerns for the environment or health became part of the mindset of all milieus without much difference. This SINUS Institute study is an example of another resource available for entrepreneurship and innovation education: social science research.

4 SINUS-Institute is a well-established social science and market research institute in Heidelberg, Germany (http://www.sinus-institut.de/en/).

In the international discussion, the phrase “German Angst” has been established over the years. Especially a certain degree of technophobia has been detected during the 1980s and 1990s. The use of nuclear energy and the ban of genetically modified crops were at the heart of this discussion. In a number of national surveys people were asked: “What do you think, are technologies in general rather boon or bane?” The answers are given in the chart below:

Fig 5. New Technologies “boon or bane” – German National Surveys 1966-1998



These data demonstrate that people are growingly concerned about technologies. The number of people who dislike all technologies (rather bane) is on a constant level. But the positive side of the spectrum is losing importance. Those who show some ambivalence are growing, which implies increasing importance placed on various means to make technology safer and reduce the number of broken eggs. Research in the U.S. and other polities measures technophobia and other attitudes toward technology and provides insights that are useful for making sense of responses that seem counterintuitive or even illogical from a technical expert’s perspective.

Formal technology assessment has its strength at the more general level of technological development, asking for a participative decision about the pros and cons of a technology: the use of nano-materials, nuclear energy or genetically modified crops. Taking the stages shown in the illustration of the Collingridge Dilemma, technology assessment is placed close to basic research and technology development. Innovations and technology analysis are seen as an essential part of the product development process and the implementation and application of products. Therefore, the firm and its innovation processes are in focus when negative side effects have to be minimized. The central question is: How to shape the product in a most favorable way avoiding negative impacts and effects. To do so, engineering has to cope with those values which were mentioned by the VDI 3780 regulation in Germany.

5. Conclusion: The Potential for Strengthening the Entrepreneurial Approach to Technological Innovation through Cross-Cultural Collaboration

In brief, the argument presented here is that both the U.S. and EU have experienced cultural shifts that increase awareness of the need to consider potential risks early in the technology development process. In Germany/the EU, the legal/regulatory framework requires firms to engage in technology assessment in the early stages of new product development. The Precautionary Principle as implemented in the EU, then, gives firms an incentive to develop evidence *before* other large investments have been made and more or less eliminates the possibility of a firm making what Resnick calls a “decision under ignorance.” It changes the burden of proof. This means that engineers need to be educated so that they can consider multiple stakeholders, values, etc. when they are on the job. While the accreditation outcomes in Germany are quite similar to those in the U.S., the curricula in Germany tend to include a few courses such as technical communication, project management, and, perhaps, a course in leadership or innovation management. In the U.S., the regulatory framework does not put the same pressures on the early stages of product development, but the curricula of engineering schools more substantially integrated health, safety, and environmental concerns into the design process (as exemplified in the major design experience required by ABET).

These differences between the U.S. and EU are thus more subtle and less stark than they might appear when we are operating at the level of public perception. Innovators operating across the two polities who did not get beyond the common view might overestimate the differences between the two and miss the common ground that provides the potential for the kind of regulatory coherence that would be required to make the TTIP and other forms of international cooperation possible. As we hope this paper makes clear, it takes a great deal of research and analysis to understand the complexities of differences in legal and regulatory systems and how those systems relate to differences in values and preferences. From a curricular point of view, we cannot reasonably expect to provide students with all the kinds of knowledge they would need to collaborate across all polities globally (any more than we could expect them to learn all the languages their engineering collaborators might speak). We can, however, present them with case studies such as the one offered in this paper to alert them to the complexity they may encounter and the resources that are available for making that complexity manageable.

Similarly, as the last section of this paper demonstrates, we can provide them with models and research foundations that apply broadly across all domains of engineering innovation and be used to develop a useful understanding of the particular legal, regulatory, and cultural contexts in which they wish to innovate.

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