SELECTION AND DEVELOPMENT OF INNOVATIVE DESIGN ALTERNATIVES

ETHICAL, SOCIAL AND UNCERTAINTY ISSUES

JOHANNES FRANCISCUS JACOBS

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If you have a distillation column and I have a tubular reactor and we exchange - then you and I still each have a single piece of process equipment. In the contrary, if you have an idea for safer designs and I know a way to make production more sustainable and we exchange - then each of us will have two design ideas.

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Chapter 1

If man realizes that technology is within reach, he achieves it. Like its damn near instinctive.

Motoko Kusanagi – Ghost in the Shell

Chapter 1: Introduction

Imagine that you are design engineer working for a company that produces different kinds of paints and coatings. You are starting on a new design project that is based on academic research, that was picked up by the development department. Let us suppose that this research is based on the publication of Natalio et al. (2012) in Nature Nanotechnology. The development department picked up on this research, because it was heralded as the discovery that "*could lead to the development of new protective, antifouling coatings and paints that are less damaging to the environment than the ship coatings currently used*" (ScienceDaily 2012). The research was done by researchers from the Institut für Anorganische Chemie und Analytische Chemie (Johannes Gutenberg University), Van't Hoff Institute for Molecular Sciences (University of Amsterdam), and Max Planck Institute for Chemistry (Mainz). The research team studied the prevention of unwanted biofouling of ship hulls, sea buoys, jetties, and offshore platforms by marine organisms such as algae, bacteria, barnacles, grasses, and mussels.

The researchers took their inspiration from the natural occurring enzymes preventing bacteria to grow on the surface of seaweeds (Natalio 2012). The seaweed enzymes can kill the bacteria by their biocidal nature, because these vanadium haloperoxidases catalyse a reaction that forms the disinfecting substance hypobromous acid (HOBr). The researchers mimicked this catalysis by rod shaped nanoparticles of vanadium pentoxide (V_2O_5). After testing the anti-bacterial activity of the V_2O_5 nanoparticles, the researchers formulated a greenish coloured paint that contains these nanoparticles. Painted steel plates were tested in seawater and the test results indicated that the paint with V_2O_5 nanoparticles prevented the formation of biofouling.

The development department identified that the research into nanotechnology based anti-fouling paint additives by Natalio et al. (2012) seems to present a potential for commercial application, because antifouling systems reduce the cost of transportation, lower ship delays due to defouling, and reduce the amount of underperformance claims. As a design engineer it is your task to design a commercial marine paint formulation and its large-scale production process. Let us consider what needs to be addressed to tackle this design assignment.

First of all, it is important to look at existing antifouling systems, in order to prevent the reinvention of the wheel. Currently, most protective coatings in the marine industry are in the form of paints. Foul release coatings create a smooth surface that limits the ability of fouling organism to form a strong bond with the surface. The coating thus does not kill the fouling organisms, but makes it harder for the organisms to get a grip. These non-stick coatings allow the organisms to be dislodged when the ship moves faster than a specific speed (typically above 15 to 20 knots). For boats unable to reach the required speed, such as most sailboats and electric boats, the biofouling must be scrubbed away. This type of coating does not resist biofouling and therefore, it is inappropriate for static marine structures and of limited use if the vessel is dockside.

An alternative antifouling system is topcoat paints that contain additives that act as a biocide. Tin containing additives (e.g. tributyltin) were widely applied in antifouling paints until this group of substances was found to have a negative environmental impact (Terlizzi 2001; Strand 2005), resulting in bans by the International Maritime Organization (International Convention on the Control of Harmful Antifouling Systems on Ships) as well as the European Union (Regulation 782/2003/EC). The negative environmental impact of tin based paints is mainly the result of the leaching of the biocide from the paint into the marine ecosystem. The biocides thus not only affect biofouling on the hull, but they are also released into the surrounding water and can reach toxic levels for marine organisms in the water and bottom sediment. The bans led to the use of substitutes, such as copper and zinc based additives. The International Maritime Organisation currently approves various copper additives to paints for the prevention of biofouling. For a long time, it has been known that copper can be used to keep barnacles at bay; copper sheets were already used in the Age of Sail for this purpose. However, these copper based additives are also considered to have harmful effects on marine life (Bao 2011; Guardiola 2012) and thus have been banned for recreational boats in several places (e.g. Denmark, the Netherlands, Sweden, and Washington State). Currently, zinc based additives are also utilised as a biocide in antifouling paints. These zinc-containing paints are suspected of negative environmental effects, however, there is a lack of data on their toxicity (Guardiola 2012). Nonetheless, the Swedish Chemicals Agency (KemI) has labelled these additives as pesticides and prohibited sales and use of zinc oxide-based antifouling products until its use has been authorised.

The researchers of the V_2O_5 nanoparticles paper (Natalio 2012) were aware that toxicity of antifouling additives on marine life is an issue for commercialisation and therefore conducted acute toxicity tests on brine shrimp larvae. The research showed that the nanomaterial was less toxic than copper pyrithiones, which are approved anti-fouling substance in paints. Therefore, the researchers concluded that the V_2O_5 nanoparticles are "*not toxic to marine biota*" (Natalio 2012, p530). Despite these promising results of low acute toxicity, the effects on other marine species and long-term effects on marine life have not been investigated. The researchers also investigated the leaching of vanadium from the paint, in nine-week experiments. Their results indicate that vanadium leaching takes place, but the concentration reached in the water is "*representing no environment threat*" (Natalio 2012, p533). The results do not indicate whether the leached vanadium is dissolved or still in its V_2O_5 nanoparticle form. Furthermore, it is unclear how much vanadium will leach in the long-term and what the effects are of accumulated V_2O_5 nanoparticles in the marine environment. Another issue is the durability of the V_2O_5 nanoparticles containing paint. In the research by Natalio et al. (2012) the paint was tested for two months and it is thus unclear how much longer the V_2O_5 nanoparticles retain their antifouling effect. Finally, it has not been investigated what the environmental burden is when the paint is removed and discarded.

As a design engineer you are confronted with the issue that the negative environmental effects of V_2O_5 nanoparticles are not fully clear. However, the antifouling properties of the paint could also yield environment benefits. The biofouling of the ship hulls leads to increased hydrodynamic drag by frictional resistance of the water against the hull and, as consequence, results into higher fuel consumption to maintain the ship's speed. Hence, antifouling additives in ship coatings can help reduce combustion emissions. The increased hull resistance also increases wear on propulsion systems due to the additional work that is required. Anti-corrosion coatings that protect the hull can be damaged by biofouling. The resulting wear and damage leads to more repair and maintenance, which is economically and environmentally undesired. Another environmental advantage of antifouling systems is that the coating prevents the translocation of biofouling organism, because the organisms cannot hitch a ride on the vessel. Introducing alien species could have detrimental effects on existing aquatic ecosystems, because the nonindigenous organism might compete with native species for ecological niches and compromise biodiversity. All in all, it is unclear for you as a design engineer, if the potential harm to the environment of the V_2O_5 nanoparticles is greater than the potential environmental benefits of less biofouling of ship hulls.

Besides being benign to the environment, it is essential for a design engineer to consider the potential safety of workers in the production, application, removal and discharge of the V_2O_5 nanoparticles containing paint. The toxic effect to humans is hard to evaluate, since only a limited amount of research has been done on the toxicity of vanadium oxide particle. Research on human colon cells "*demonstrated a significant cytotoxicity*" (Rhoads 2010, p295) and investigations on rodent cells indicated that toxicity is dependent on the cells functional adaptation based on its origin (Ivankovic 2006). Due to this limited information about human toxicity it is unclear for the designer how to formulate the paint or shape the V_2O_5 nanoparticle to make it safer for workers as well as retain its anti-fouling properties. On the other hand, antifouling coatings promote the safety of the ship's crew, because it prevents manoeuvrability issues of the vessel. Biofouling of a surface is not evenly distributed, because the fouling organisms exploit ecological niches on the ship's hull. The varying amount of biofouling leads to poorer manoeuvrability performance that can result in dangerous situations.

When engineering a protective coating there also are other aspects that require attention, besides the environmental acceptability, health effects of workers, and safety considerations. For example, the coating should be capable to handle the expansion and contraction of the underlying surface due to temperature differences and stress on the material. When the paint is applied, the formulation needs to be compatible with application mechanism (e.g. brushing, rolling, or spraying) as well as having a short curing time. Furthermore, the antifouling coating should be economically viable, compatible with underlying systems, overcoatable, and resistant to abrasion (Chambers 2006). It is very hard to simultaneously satisfy all these aspects and trade-off need to be made. For example, to make a topcoat resistant to scratches it needs to be hard. Such a hard coating is not very flexible and will crack with rapid expansion and contraction of the underlying surface. In formulating a marine paint it is thus necessary to make trade-offs. The above illustrates that a design engineer is required to make decisions while designing a new paint formulation and its production process, even though not all the relevant information is available.

The above example gives an impression of the aspects that need to be addressed during the engineering design of a novel antifouling coating formulation and its production process. The design raises questions about the way an innovative product or process can be engineered. How can a design engineer anticipate effects of the product or process when so much is uncertain and unknown? Are there any methods/tools available to support making design decisions under such uncertainty? Can an engineered product be made in such a way that it is adaptable to minimise negative effects arising later on? What is the responsibility of a design engineer of an innovative product, if issues arise during its use? The issues raised by the example clearly highlights that a designer of innovative products or process is working under uncertainties while being faced by various social and ethical issues. The addressing of social and ethical issues under conditions of high uncertainty in innovative engineering design is the main topic of this thesis.

1.1. Motivation

Engineering design shapes the development of new technologies. Design impacts the way society and technology will develop, because it affects what kind of possibilities and consequences will arise. Hence, engineering design is ethically and socially relevant. In the current literature attention has been given to the way ethical and social issues can be addressed in engineering design. An approach for considering ethical issues in the design process has been proposed under the name of Value Sensitive Design (VSD). In this approach, human values, such as autonomy, human well being, human dignity, justice, privacy, and welfare, are expressed and then incorporated into the design of information technology, such as computer systems and software. VSD is an approach that works by mapping human values and integrating the value considerations into the system (Friedman et al. 2006; Van den Hoven 2009). Other approaches focus on the incorporation of values related to environmental sustainability in the fields of industrial and architectural design (Birkeland 2002; Bhamra and Lofthouse 2007). In universal, inclusive, or accessible design approaches the aim is to include the value of equality into industrial design by principles of ergonomics, flexibility, perception, and cognition (Keates and Clarkson 2003; Erlandson 2008). Other authors have described approaches to incorporate social and ethical considerations in engineering education. Ethics is considered a compulsory topic in most engineering curricula and the VSD approach has been used in case studies to teaching ethics in design projects (Cummings 2006). Other approaches use historical case studies (Lynch and Kline 2007) or honour codes (Fleischmann 2004) to educate engineering students about ethics. Alternatively, Berne and Schummer (2005) present a way to use science fiction for the teaching about the societal and ethical implication of nanotechnology. In these various approaches to incorporate ethical values in engineering design and engineering curricula, little to no attention has been paid to innovative engineering design. Particularly, the effect of uncertainties that are typical of innovative design on socially and ethically laden design consideration have not been explored.

In the designing of new technological products and processes social and ethical issues emerge, as shown in the example of the development of vanadium pentoxide nanoparticles based antifouling coatings. Innovative engineering design is different from normal design. Normal design is in a sense just business-as-usual for the design engineer; nothing out of the ordinary is brought to the table. Vincenti (1992) describes normal design, as a design task in which the engineer already has a good idea about how the designed device will work and look like. In other words, in normal design work there is a kind of accepted tradition in designing that follows existing formal and informal rules. I will take a normal design, along the lines of the description provided by Van Gorp (2005), as a design in which the configuration, function, and operation principle are kept similar to previously existing designs. In contrast, when the accepted function and/or structure are changed or unknown we can speak of innovative design. The trade-mark of an innovative design is its novelty or newness, in similar vein to the notion of invention. Hence, innovative design work aims at creating a unique process or product that may be related to already existing designs by non-obvious alterations. The issues as indicated in the Collingridge dilemma (Collingridge 1980) complicate the dealing with social and ethical issues in innovative design. The dilemma is an issue of efforts to control technological development by a combination of the problem of power and the problem of information. The Collingridge dilemma highlights that at the initial stage of development, when the development is easily steerable, there is insufficient information to act upon; whereas in later phases, when issues become more evident, the possibility to alter the technology is constrained.

In her work Van Gorp (2005) has studied how engineers deal with safety and sustainability issues in design practise. She discovered that design engineers fall back on a regulative framework (formal and legal rules) for making ethically relevant design decision in normal design work. In normal design there is experience with very similar processes, products, or devices and the designer has a good notion of the social and ethical issues that play a role and can often rely on a regulative framework. In contrast, innovative design leaves the designers with no clear knowledge about the effects the design will bring about, because it does not yet exist. Hence, there is no clear view on the social and ethical issues in the application of the device or its long-term effects. Moreover, there is no regulative framework to support the designer. The lack of knowledge and absence of an appropriate regulative framework demands a larger responsibility by the design engineer in innovative design (Van Gorp 2005). However, Van Gorp did not study how engineers deal with ethical issues in relation to uncertainties. This study sets out to fill this gap. It will explore the way engineers approach social and ethical issues under the uncertainties that are typical of innovative design.

The uncertainties in innovative design are not limited to statistical probabilities. Even if the design engineer is aware of a possible effect of the design, he/she cannot attribute probabilities to the likelihood of occurrence of these effects due to the limited knowledge that is available. In these cases, we speak of 'known unknowns' that are the result of incomplete information. The newness of a design may also result in ignorance about possibility of certain outcomes; in such cases we do not know all possible consequences. In other words, 'unknown unknowns' are the cause of the faced uncertainty. Yet another way that makes uncertainties of innovative engineering difficult to address is the complexity of causal relations due to the large number of interacting variables that govern the relation between the designed processes, products, or devices and its effect. Ambiguities also play a role in uncertainties that are typical of innovative design. We speak of ambiguity, if something can be understood in various manners. An example is that sometimes various reasonable interpretations can be given to preliminary research data that is available for innovative design. All in all, there are various types of uncertainty that are faced in innovative design, which are not easily addressed in a statistical manner. It is thus evident from the above description that inquiry into social and ethical laden innovative design practices needs to incorporate these typical uncertainties.

1.2. Aim and Scope

In the current literature little attention has been given to social and ethical issues, especially in relation to the uncertainties that are typical of in innovative engineering design practice. The *aim of this thesis* is: to contribute to the adequate dealing with social and ethical issues in innovative engineering design. To achieve this aim, the focus will be on two more specific challenges in dealing with ethical issues in innovative design: (1) the challenge to choose the best design concept in the early design stages, and (2) the challenge to develop a design that is robust with respect to relevant uncertainties.

The focus on these two challenges is inspired by a general analysis of the major elements of the design process. In the engineering design process, a blueprint of the system or the physical structure is created that forms the embodiment of the design goals. There are many ways to describe the design process. Numerous design activities have been identified, such as abstracting, analysing, composing, decision-making, exploring, generating, modelling, planning, selecting, simulating, and synthesising (Sim and Duffy 2003). Also various design stages have been identified, for example feasibility assessment, preliminary design, conceptual design, embodiment design, detailed design, and production planning (Cross 2000). In the current literature, two competing perspectives on the engineering design process can be found (Ralph 2010). The reason-centric perspective has its roots in the work of Simon (1969) who described the design process as problem solving. In this perceptive the design process is a plan-driven way to find a design solution to a given design problem within a field of constraints. The perspective has received various critiques. For example, Holt and co-authors (1985) have argued that reducing the engineering design process into purely problem solving will result in overlooking specific aspects of design work, such as creative idea generation, information gathering, and social interaction. Some of these critiques have been incorporated in the form of the ill-structured problem (Simon 1973) and co-evolution of problem and solution (Dorst and Cross 2001).

The competing view, action-centric perspective, finds its roots in the many critiques to the reason-centric perspective and most notably in the work of Schön (1983). In the action-centric perspective, thinking and action are complementary. In this view the designer reflects on its own practice by shifting between conceptualising (imposing coherence to an uncertain and ill-defined situation), moving (actions intended to improve the situation), and appraising moves (identifying consequences and implication of the action).

Despite different suppositions, both perspectives are similar in some ways (Ralph 2010). Among others, the perspectives share two general design elements, knowingly the evaluation and generation of design concepts. The thesis will therefore focus on the challenges that these two general design elements generate for design engineers in dealing with social and ethical concerns in innovative design practice. The two challenges in dealing with these issues in innovative engineering design under uncertainty can be summarised as follows: (1) the selection of the 'best' design concept from among a set of alternatives and (2) the development of a 'robust' design alternative.

The first challenge is the selection of the 'best' design concept from among a set of alternatives for further design, construction, and application. In a design process, the design engineers usually generate several alternative designs. All these alternatives present a way of getting to the desired end result and incorporate different kinds of uncertainties. In practice not all of these alternatives can be fully designed into detail due to budget and time constrains. Therefore, design engineers need to decide what alternative is the 'best' design concept for further development. However, in innovative design work it is a challenge to select the 'best' alternative, because the designer is faced with social and ethical issues under uncertainties.

This challenge of selection is dealt with in the first part of the thesis (chapters 2-4). There is an existing practice on making selections in engineering design with selection tools, such as the analytic hierarchy process, Pahl & Beitz method, Pugh's concept selection, quality function deployment, and weighted-product method (Akao 2004; Eggert 2005; Hauser and Clausing 1988; Pahl and Beitz 2005; Saaty 1980). All these tools used a kind of decision matrix and will therefore be referred to as matrix tools. The matrix tools compare design alternatives based on performance measures that are related to a set of criteria. The focus of this study is on (a) the critical assessment of the matrix tool in relation to the social and ethical aspects and the uncertainties that are typical of innovative design, (b) the ethnographic investigation of the function and evaluation of the matrix tool by design engineers in design practice, and (c) the ethnographic investigation of the way performance measures can be obtained for ethically laden criteria such as safety.

The second challenge is the development of the design idea into a design alternative that is robust to the uncertainties that surround innovative design work. Robustness in this sense relates to the reduction of vulnerabilities to uncertain consequences, adaptability to possible future states, lowering sensitivity to assumptions, and satisfactory performance over a large range of scenarios.

This challenge is tackled in the second part of the thesis (chapters 5-7). The recent developments in nanotechnology will be used, since these advances are the most recent example of technological innovation under large uncertainties. To place the investigation on solid ground, the social and ethical issues in the development of nanotechnology are discussed. Since nanotechnology is a very new field, there is no real prominent existing regulative framework to deal with social and ethical issues. Van Gorp (2005) has shown that when such a regulative framework is missing design engineers will deal with social and ethical issues by using general ethical values and principles, such as safety and sustainability. The focus in this thesis is, therefore, on the development of an approach that can apply such values and principles in innovative design work. This thesis uses two approaches that already have been developed in other fields of engineering design for incorporating social and ethical issues in engineering design and it is investigated how these can be modified for innovative design work. The first approach is the green principles (Anastas and Warner 1998), which have been employed in the chemical industry to address environmental issues and incorporate sustainability values by diminishing and abolishing of the usage and production of harmful substances. The second utilised approach is social experimentation (Van de Poel 2009). In this approach the moral acceptability of a technological development can be evaluated by considering it a large-scale experiment on society. In these two ways it is studied how to alter and develop approaches, which address social and ethical issues in light of the uncertainties that are typical of innovative design.

The *scope of this thesis* will be limited to the innovative product and process development in the field of nanotechnology and (bio)chemical technology. This scope is chosen due to the high prominence of ethical and social issues as well as the current rapid development of both technological fields.

1.3. Research Question

The *main research question of this thesis* is: how can design engineers adequately deal with the challenges raised by social and ethical issues under the uncertainties that are typical of innovative design practice? As indicated in section 1.2, the focus will be on two more specific challenges in answering the research question. This leads to the following more specific research questions:

1. How can engineers select the best design alternative for further detail design in the conceptual design phase in innovative design process taking into account ethical and social issues?
2. How can design engineers develop ethically and socially acceptable design alternatives that are robust to the uncertainties that are typical of innovative design?

1.4. Research Methodology

The study presented in this thesis has an exploratory nature, because relatively little is known about the way design engineers can and should deal with socially and ethically laden issues under uncertainty that is typical of innovative design practice. Moreover, most innovative design work is done by closed teams in corporate settings under strict confidentiality; therefore, data on the subject is difficult to collect. Exploratory research is well suited to investigate such new phenomena without the need of formulating explicit hypotheses beforehand on the basis of the literature. Exploratory research also provides ample qualitative study methods for gathering initial information to gain familiarity with and insight into the phenomenon.

Different research methods are required in order to answer the research questions of this thesis. The first research question, about selecting the best design concept from among a set of alternatives under uncertainty that is typical of innovative design (chapters 2-4), requires a combination of analysis of methodological adequacy and exploratory ethnographic study on the existing practice. In chapter 2, a *critical methodological analysis* of a frequently applied selection tool, which includes social and ethical aspects, is done to identify possible methodological difficulties. This analysis mainly draws on the existing design literature and social choice theory. In chapter 3, the practical use of the selection tool is investigated in an *exploratory ethnographic study*. In the ethnographic study three qualitative techniques, notably quasi-participant observation, document analysis, and semi-structured interviews, have been used complementary to allow for the validation of the results by triangulation (Ball and Ormerod 2000; Yin 2009). Furthermore, the use of multiple techniques also allows the study of the subject from various perspectives, which is essential if tacit knowledge and group dynamics are involved (López-Mesa and Byland 2011). Quasi-participant observation also provides a way to avoid undue influence on the design practice by presenting the investigator as an engineer among engineers (Van Gorp 2005). In this way, the design team did not feel compelled to simplify or water down explanations, and it provides a normal working atmosphere. The investigator took the role of interested engineering colleague having no influence on the project and no say in the assessment of the end result. The role of listener was assumed during the design meetings as well as conferences with advisors. The design team documents the use and results of the selection tool. Therefore, qualitative document analysis techniques were used to investigate the final design reports as well as intermediate documents and materials. After the design work had been finished the design team was interviewed as a group. In this semi-structured interview the design team was presented with the preliminary results of their own design project and were asked, if these research results presented the reality of what had happened. In doing so, the semi-structured interview presented a new perspective on the design project as well as served as a regulating method for the non-controlled nature of the exploratory ethnographic observation and document analysis. Multiple design projects were selected for this ethnographic study from the field of (bio)chemical technology. All design projects were conceptual of nature and were selected on the innovativeness of the proposed objectives in such a way that the projects have a similar level of uncertainty and complexity. Chapter 4 applies the same exploratory ethnographic approach in order to investigate the way value laden performance measures are used in innovative design practice.

The second research question, about the development of ethically and socially acceptable design alternatives that are robust to the uncertainties that are typical of innovative design (chapters 5-7), requires an *exploratory ethical inquiry* approach. Nanotechnology was selected as the focus for the ethical inquiry, because it is a very novel field and it encompasses many examples of innovative design under uncertainty. The field of nanotechnology is very diverse and is a current example of innovative technology with the type of uncertainties that are the focus of in this thesis. In chapter 5, a critical literature study is done to ground the subsequent enquiry by identifying the various social and ethical issues that play a roll in the development and application of nanotechnology. In order to obtain clarity about the uncertainties that surround these issues, a distinction is made between the short and long term. In the short term the study is about values that play a role in the current design and marketing of nanotechnological artefacts, while in the long term the view extends to envisioned applications in the distant future. In chapter 6, an inquiry is done about the ability to adapt existing approaches for addressing environmental, health, and safety issues in engineering design in such a way that these approaches can be utilised for innovative design project. The inquiry is concentrated on the application of nano-sized titanium dioxide (TiO_2) particles in sunscreens. The particular focus on nano-sized titanium dioxide was chosen in light of the ample natural science research work that provides a clear understanding of the basic physical properties and laboratory scale production of the nano-particle. Nonetheless, the application of nano-sized titanium dioxide in the cosmetic industry was in its initial phases, so it provided a good illustration of innovative design. The focus provides the typical uncertainties of innovative design after very basic physical properties and lab-scale production has been established. The focus on the sunscreen application allows for a comparison with existing sunscreens, which do not contain nano-particles in such a way that the effects of uncertainties of innovative design become apparent. Chapter 7 concentrates on the same application of nanotechnology, but the enquiry delves into the possibility to create approaches that evaluate the acceptability of innovative design alternatives.

1.5. Thesis Outline

This thesis consists of six chapters which already appeared elsewhere or were submitted as separate and independent papers. As the chapters are mostly identical to the original texts there is some unavoidable overlap between them. For the same reason, there is also some slight difference in terminology between the chapters; where relevant this will be explicated. The thesis addresses the two challenges that were identified above and each requires a specific research approach as explained. The first challenge is that of selecting the best design concept from among a set of alternatives and it is addressed in the first part, consisting of chapters 2, 3 and 4. Chapters 5, 6 and 7 comprise the second part that deals with the challenge of developing robust design alternatives. To clarify the way the chapters contribute to the main line of this thesis the six chapters are outlined below.

Chapter 2: Clarifying the debate on selection methods for engineering - Arrow's impossibility theorem, design performances, and information basis

The first chapter deals with the selection of design alternatives. It introduces selection tools that use a matrix structure as used in existing engineering design practice, and it surveys the current literature about such selection tools. It analyses the on-going debate on the validity of such selection tools and gives a critical assessment on the tool's usability under uncertainty. The validity of the tools has been discussed in the literature in relation to Arrow's impossibility theorem. This theorem sets limits to any attempt to make a selection tool that satisfies a basic set of rudimentary conditions to prevent inconsistent or paradoxical outcomes. This theorem originally comes from social choice theory and I argue that it can affect selection tools in engineering practice in several ways, once the theorem is properly adapted to the context of engineering design. The theorem thus presents severe limitations to the usability of matrix selection methods to indicate the best solution. These limitations are even more restrictive in the case of innovative design due to the type of uncertainties that are faced. In innovative design, the decision maker has to predict the behaviour of the designed artefact and has to envision its application as well as the effect it will bring about. However, this kind of forecasting is clouded by lack of information and unknowns. Another difficulty of the selection method is the problem of making comparisons among the various ethically and socially relevant criteria that play a role in the selection process. This combination of methodological difficulties with calculative selection tools make it questionable whether these tools are adequate for selecting the best design alternative in an innovative design process.

Chapter 3: Usage and evaluation of decision matrices - Innovative conceptual design

The second chapter presents the results of six empirical studies on innovative (bio)chemical engineering design projects at Delft University of Technology. In these studies, it was investigated how the designing engineers use the matrix tools in innovative design practice. The results show that the studied engineers did not exactly use the tools' methodology as assumed in the literature. In the literature, as surveyed in chapter 2, it is assumed that matrix-based selection tools are used to make a choice, or at least justify the selection between design alternatives. In other words, it is presumed that the tool has a prescriptive or descriptive use. However, the results of the empirical study show that in practice, the tool is not used in this way. It was observed that the tool is mainly used to support the judgment formation process in three distinctive ways. First of all, the explicit and visual nature of the matrix provides insight into the design problem. Secondly, the matrix stimulates creativity by showing the strengths and weaknesses of the various design alternatives on various criteria. Finally, the matrix method is used as a communication tool that supports the decision making process with the other parties involved. This implies that the current debate in literature (as described in chapter 2) should also consider the discovered practical application by allowing pragmatic evaluation criteria to play a role in addition to coherence and correspondence criteria, which currently dominate the debate on the validity of the selection tools. Furthermore, it also implies that the methodological difficulties of the selection tools have a low impact on the design process, as the practical application of the tool is not hindered by the difficulties and leads to successful designs according to the engineers.

Chapter 4: The Fire and Explosion Index in innovative engineering design - Methodological and application issues

This chapter concludes the part on selection of design alternatives. The selection tools used in engineering practice, as described in chapter 2 and 3, use performance measures. The measures indicate how well the design alternatives perform on a given criterion. Some of the used criteria are value laden, such as safety and sustainability. However, none of the selection tools is particular clear about how to measure performance. Generally, it is assumed that the designer is able to assess the performance of the alternative based on the limited available knowledge, supplemented with experience, estimations, and heuristics. Nevertheless, there are methods available that assess a design on a specific criterion and could be helpful to measure performance. In the six design projects at Delft University of Technology, which were also studied in chapter 3, the design engineers used the Fire and Explosion Index (F&EI). This index tools is widely used to assess the safety of a design in the conceptual design stage. However, my empirical evidence shows that the F&EI is not used in a way that makes it compatible with the identified use of the selection tool (as described in chapter 3). Furthermore, our findings suggest that the F&EI is not a representative performance measure of safety, because it does not provide an adequate basis for comparison between design alternatives. Finally, it was found that the tool is not compatible with the uncertainties of conceptual innovative design work. In chapter 4, it is concluded that the F&EI is not a practical performance measure of safety for the selection of design alternatives. Nonetheless, indexes can be a starting point to build methods suitable for performance measures.

Chapter 5: Design for values - Nanotechnology

The first chapter on the development of robust design alternatives gives an overview of the social and ethical issues in the field of nanotechnology. In order to develop a robust design, it is important to know the central values and value issues that are at stake. The issues that are considered are divided between short-term and long-term issues. As nanotechnology is an enabling technology, most of the values are not new or unique to nanotechnology. Nonetheless, I argue that nanotechnology can result in new issues by the way nanotechnology combines values, brings values into conflict, and places value issues in new contexts. The analysis shows that a whole array of issues is at stake and that these can best be investigated from the perspective of specific applications. In the short-term an important role is played by values such as equality, justice, privacy, responsibility, safety, and sustainability, while in the long-term the focus will be on values such as human dignity, integrity of human nature, and intergenerational justice. Some approaches to incorporate values, such as design for safety and design for sustainably, have been developed already for short-term nanotechnology applications. Approaches to develop a robust design in the long term are hindered by the possibility that category boundaries, which ground and explain the values, will get blurred. Nonetheless, it is argued that scenario techniques can provide some clarity in these situations. An example is given of the application of nanoparticles in sunscreens and another example is given of nanotechnology-based enhancement of human capabilities in the form of cyborgs.

Chapter 6: Towards safety and sustainability by design - Nano-sized TiO_2 in sunscreens

The chapter describes an approach to design robust alternatives that address environmental, health, and safety (EHS) issues. This development of such an approach is complicated due to the large diversity of nanotechnological applications, the narrow focus of EHS research on specific nanomaterials that are currently applied in products, and the dilemma of social control (Collingridge dilemma). In light of a focus on the whole production chain and retrospective learning, the established twelve green principles of green chemistry are translated and applied to the innovative field of nanotechnology. The developed green nanoprinciples consist of four concepts (product safety, low environmental impact, material & energy efficiency, and process safety) that can be applied in the design of robust nanotechnological applications. The approach copes with the identified hurdles and can be applied in conjunction with other ways to deal with the Collingridge dilemma, such as forecasting techniques and technological adaption. In the chapter, the use of the green nanotechnology approach is illustrated with a study on titanium dioxide particles for cosmetic sunscreen applications. The case shows that the application of the approach broadens the focus of the EHS research, and is general enough to handle the heterogeneity of the field of nanotechnology. All in all, the chapter makes a case for the adaptation of existing approaches so they are able to deal with uncertainty that are typical of innovative technologies.

Chapter 7: Sunscreens with titanium dioxide (TiO_2) nano-particles - A societal experiment

The final chapter on the development of robust design alternatives provides an approach to evaluate the moral acceptability of alternatives under uncertainty. In this approach, the development of a design alternative is conceptualised as a societal experiment of which the consequences cannot be fully assessed due to the existing uncertainties that surround the introduction of an innovative technology into society. Only after its introduction and penetration into society is it possible to fully assess the consequences; as such, the introduction of a novel technology is a kind of experiment. The approach evaluates the acceptability of such a societal experiment on the basis of four conditions (absence of alternatives, controllability, informed involvement, continued re-evaluation). The approach is again illustrated with a study on titanium dioxide nano-particles for cosmetic sunscreen applications. The study indicates that all four acceptability conditions laid out in the approach are violated by the current introduction of nano-sized titanium dioxide containing sunscreens. Hence, the introduction is arguably an example of an unacceptable societal experiment. Based on the results of the approach five actions are recommended to remedy the situation (closing the gap, setup monitoring tools, continuing review, designing for safety, and regulative improvements). The chapter thus shows that it is possible to develop approaches that can support the development of robust design alternatives.

Chapter 8: Discussion and outlook

In this closing chapter, the main conclusions of the previous chapters are considered in relation to the overall aim of this thesis. It discusses the way engineers do and can adequately deal with the challenges raised by social and ethical issues under uncertainty that is typical of innovative design in the fields of nanotechnology and (bio)chemical technology in relation to the selection of design alternative and developing robust designs. The main findings are condensed in the form of six propositions. Lastly, an outlook is provided and recommendations for further research are given.

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Chapter 2

Okay, the answer to the ultimate question of life, the universe, and everything is... 42.

Deep Thought – The Hitchhiker's Guide to the Galaxy

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Chapter 2: Clarifying the Debate on Selection Methods for Engineering - Arrow's Impossibility Theorem, Design Performances, and Information Basis

Abstract

To demystify the debate about the validity of selection methods that utilize aggregation procedures, it is necessary that contributors to the debate are explicit about (a) their personal goals and (b) their methodological aims. We introduce three additional points of clarification: (1) the need to differentiate between the aggregation of preferences and of performances, (2) the application of Arrow's theorem to performance measures rather than to preferences, and (3) the assumptions made about the information that is available in applying selection methods. The debate about decision methods in engineering design would be improved if all contributors were more explicit about these issues.

2.1. Introduction

In his editorial "My method is better!", Reich (2010) has pointed out that implicit presuppositions and arguments need to be laid out in the open to enable a serious and reflective debate on the validity of methods for dealing with multi-criteria problems in engineering design. In his analysis of the debate, Reich suggested that misinterpretations could be avoided if authors clearly state which kind of goals they strive for when presenting certain arguments. He makes a distinction between the goal to improve design practice and the goal to obtain theoretical rigor. Katsikopoulos (2009, 2012) also analyzed the debate and indicates an important distinction between methodological aims in order to achieve coherence or correspondence.[1] He argues that the debate can be improved if authors would acknowledge this distinction.

Several authors have thus investigated the debate and their suggestions will contribute to the development of a more reflective debate. However, we want to point out some further unclarities and implicit assumptions that also need to be addressed to engage in a fully open debate on matrix-based selection methods.

This chapter is structured as follows. In section two, the selection methods with a matrix-based structure, which are used in engineering design practice to deal with multicriteria problems, are described. We argue that Arrow's impossibility theorem affects decision-making in engineering design in two distinct ways, knowingly the aggregation of preferences and of performances. In the following section, we will modify the theorem to design performances as utilized in engineering design rather than to preferences as in Arrow's original formulation. In section four, the presumed amount of information, which is available for the multi-criteria selection problem, is discussed in terms of uncertainty, comparability, and measurability. In the final section, we will draw conclusions by suggesting several ways in which the current debate on the validity of matrix selection methods can be improved.

2.2. Preferences and Design Performances

Selecting a single or a few promising design concepts from a larger set is an important part of engineering design. The selection of the 'best' design concept(s) for further design and development is a decision-making activity that is based on various criteria, which are, in turn, based on the design specification and requirements. Various methodologies have been developed to support this type of multi-criteria selection. Methods that use a matrix structure are frequently applied in engineering design practices, for example, the analytic hierarchy process, Pahl and Beitz method, Pugh's concept selection,[2] quality function deployment, and weighted-product method (Akao 2004; Hauser and Clausing 1988; Pahl and Beitz 2005; Saaty 1980). These matrix methods visually indicate how the alternative designs are scored on various criteria by tabulating the performances of the design concepts on each criterion in a chart (see Table 2.1 for an example). A global performance structure (e.g., the scores on the three alternatives in Table 2.1) is generated by means of an aggregation procedure based on the performances on the various criteria. The global performance structure is used to guide the selection of the best alternative design for further development.

Table 2.1: Weighted-sum method with the performance measure that is based on five-point ranks

Criteria	Weight	Concept A	Concept B	Concept C
Yield	1	4	5	2
Safety	1	5	1	3
Controllability	1	4	5	2
Revenues	1	1	2	4
Score	-	14	13	11

Performance measure: 1 = inadequate, 2 = weak, 3 = satisfactory, 4 = good, 5 = excellent

This kind of decision methods is very similar to a multicriteria decision analysis in which the diverse performances are aggregated into one overall performance score. The aggregation of diverse measures into a global measure is, however, not straightforward. A similar aggregation problem has been studied within the field of voting theory and welfare economics that later formed the field of social choice theory. A huge literature was initiated, most importantly by the works of Arrow (1950) and May (1952), in which the aggregation of individual preferences into a collective preference of a group is analyzed. Various authors have claimed that the results of these theories are applicable to multi-criteria decision analysis, because the problems of social choice and multi-criteria decision analysis are structurally identical (Franssen 2005; Bouyssou et al. 2009).

One of the best-known results from social choice theory is the famous impossibility theorem that was proved by the economist Kenneth Arrow in 1950. Arrow's impossibility theorem states that if there are a finite number of individuals and there are at least three options to choose from,[3] no aggregation method can simultaneously satisfy five general conditions [see Sen (1995) for a short argumented proof or see Blackorby et al. (1984) for a geometric proof]. These conditions are as follows:

- *Collective rationality* The collective preference ordering[4] must be complete and transitive. The preference ordering is complete if it accounts for all considered options. Transitivity demands that if option A is preferred to B and B to C, A is also preferred to C.
- *Independence of irrelevant alternatives* The collective preference ordering has the same ranking of preferences among a subset of options as it would for a complete set of options.
- *Non-dictatorship* The collective preference ordering may not be determined by a single preference order.
- *Unrestricted domain* The profile of single preference orders is only restricted with respect to transitivity and completeness.
- *Weak Pareto principle* Providing that one option is preferred to another option in all single preference orders, then so must be the resulting collective preference order.

The theorem prevents the construction of a generally acceptable aggregation method that combines the single preferences into a collective preference structure, such that it represents the preferences of the group as a whole and satisfies the five conditions mentioned. Arrow's impossibility theorem only bars general procedures, because aggregation may still be possible in specific cases in which the single preferences align in very specific ways; for example, when all agents prefer the same outcome over all others or when all agents have single-peaked preferences over the considered outcomes.

In engineering design, the choice between design concepts is usually a team effort, involving designers, clients, and managers which all may have different opinions on what the 'best' design is. The combination of all these various single preferences into a final decision that selects the 'best' design among various alternatives is very similar to the type of problem that is considered in social choice theory. Various authors have identified these similarities of selections made by groups and have claimed that Arrow's impossibility theorem affects engineering design decisions in this manner (Hazelrigg 1996; Lowe and Ridgway 2000; Van de Poel 2007).

This is, however, not the only way in which Arrow's impossibility theorem affects engineering design. The aggregation problem of design performances into a global performance structure is also similar in nature to the aggregation problem of Arrow. Nonetheless, there is a difference. The most commonly applied aggregation procedures are indeed quite similar to those studied in social choice theory, but the object of aggregation is not. In the case of social choice theory, as well as in the case of group selection in engineering design, the object of aggregation is individual preferences. In contrast, in the selection of design alternatives, the object of aggregation is performances on design criteria.

To summarize, there are two distinct ways Arrow's impossibility theorem can affect decision-making in engineering design, knowingly the aggregation problem of (a) preferences and (b) design performances.

The distinction between preferences and design performances could help to clarify the existing debate. An example is the discussion in this journal about the way Arrow's impossibility theorem affects the Pugh controlled convergence method. Franssen challenges the Pugh controlled convergence method by arguing that the method "*explicitly aims to arrive at a global judgment on the relative worth of several design concepts*" (Franssen 2005, p 54) and that the "*preference order is not explicitly part of Pugh's method, but its existence must be presumed in order to understand how the designer arrives at the comparative judgments*" (Franssen 2005, p 55). Franssen, therefore, concludes that the Pugh controlled convergence method will "*run into the kind of difficulties associated with Arrow's theorem*" (Franssen 2005, p 55). In essence, he claims that the method presumes the formation of preference, even though the method uses a set of design criteria that would indicate the use of design performances. Furthermore, Franssen claims that these presumed preference structures on various criteria are aggregated to achieve a selection, which implies that the method can be challenged with the impossibility theorem.

Hazelrigg and Frey et al. also discuss the validity of the Pugh controlled convergence method. These authors disagree with each other about the question whether the Pugh method entails voting, because voting would entail the aggregation of preferences of individual persons, and as a result, the method could be challenged along the lines of Arrow's impossibility theorem. Frey and coauthors "*note that there is no voting in Pugh's method*" (Frey et al. 2009, p 43). Hazelrigg responds by pointing out that "*voting is used in the Pugh method, firstly to obtain consensus on the relative merits of candidate designs compared to the datum design and second to aggregate the symbols … in the Pugh matrix*" (Hazelrigg 2010, p 143). In a reply, Frey et al. argue against the position of Hazelrigg and hold that for building of consensus "*there is not voting in the Pugh method*" (Frey et al. 2010, p 147). The discussion is about the need of voting in the practical utilization of the Pugh controlled convergence method, since the method does not explicitly state how consensus should be reached (Pugh 1991, 1996). Pugh controlled convergence method does explicitly prevent any general attempt to aggregate the performance measures in the matrix, because it is stated that "[t]*he scores or numbers must not, in any sense, be treated as absolute; they are for guidance only and must not be summed algebraically*" (Pugh 1991, p 77). Hence, Arrow's impossibility theorem cannot be used to challenge the method on this specific point.

Another example is the debate of Hazelrigg, Franssen, Scott, and Antonsson about the importance of Arrow's impossibility theorem for engineering design in which the issue seems to be the switch between the two different measures. Hazelrigg (1996) claims that the theorem "*holds great importance to the theory of engineering design*" and that the methods "*Total Quality Management (TQM) and Quality Function Deployment (QFD), are logically inconsistent and can lead to highly* *erroneous results*" (Hazelrigg 1996, p 161). Hazelrigg claims that "*customer satisfaction, taken in the aggregate for the group of customers, does not exist*" (Hazelrigg 1996, p 163). Hence, the arguments of Hazelrigg are based on the aggregation of single preferences into a collective preference structure. Scott and Antonsson (1999) have challenged the conclusion of Hazelrigg. In the view of Scott and Antonsson, the "*engineering design decision problem is a problem of decision with multiple criteria'* (Scott and Antonsson 1999, p 218). The authors claim that in "*engineering design, there may be many people involved, but decisions still depend upon the aggregation of engineering criteria*" (Scott and Antonsson 1999, p 220). Hence, the authors are considering design performances instead of preferences. Scott and Antonsson reject the conclusions of Hazelrigg on the grounds that the conditions of Arrow's theorem are unreasonable for design performances. In turn, Franssen (2005) criticizes the conclusion of Scott and Antonsson. Franssen argues that "*Arrow's theorem applies to multi-criteria decision problems in engineering design as well*" (Franssen 2005, p 43). He claims that the aggregation problem of preferences is structurally identical to that of design performances and that the conditions are reasonable for engineering design, if interpreted in the right way.

This leads us to the following point of clarification. Although many authors have discussed the implications of Arrow's impossibility theorem on engineering design with regard to the aggregation problem of performance measures, no one has to our knowledge explicitly adapted the theorem and its conditions from the context of preferences to the context of design performances.

2.3. Impossibility Theorem for Performance Aggregation

We have adapted the five conditions of Arrow's impossibility theorem on preference aggregation into an Arrowian type of impossibility theorem for performance aggregation in engineering design[5] as follows:

- *Independence of irrelevant concepts* The global performance structure[6] between two design concepts depends only on their performances and not on the performances of other design concepts.
- *Non-dominance* The global performance may not be determined by a single performance structure.
- *Unrestricted scope* The performance structures on a single criterion as well as the global performance structure are only restricted with respect to transitivity, reflexivity, and completeness. Completeness requires that the performance structure accounts for all design concepts. A performance structure is reflective if the separate performance measure can be compared to themselves. Transitivity requires that if performance A is related to performance B and performance B in turn is related in the same way to performance C, then performance A is likewise related to performance C.[7]

- *Weak Pareto principle* Providing that one design concept is strictly better than another design concept in all the single performance structures, then so must be the resulting global performance structure for these two concepts.

The Arrowian impossibility theorem for performance aggregation in conceptual engineering design then states that *if there is a finite number of evaluation criteria and there are at least three alternative design concepts, no aggregation method can simultaneously satisfy independence of irrelevant concepts, non-dominance, unrestricted scope, and weak Pareto principle*. Similarly to the original theorem, this theorem only shows that such an aggregation is unattainable in general; so, it may still be possible in very specific cases, for instance, when all criteria give single-peaked performances over the considered design concepts. So, aggregation is possible when one design concept has the best performance on all the listed criteria. Such cases will be the exception rather than the rule in engineering design practice, in which most design decisions involve trade-offs and value-based choices. The four Arrowian conditions are thus already enough to prove the general impossibility result, even though we might wish to impose other conditions on decision-aiding tools for engineering design, such as non-manipulability (preventing unfair influence on the results) and separability (allowing reduction of the amount of design concepts in several subsequent phases).

Table 2.2: Weighted-sum method with a different performance measure that is instead based on three-point ranks

Criteria	Weight	Concept A	Concept B	Concept C
Yield	1	2	3	1
Safety	1	3	1	2
Controllability	1	2	3	1
Revenues	1	1	2	3
Score	-	8	9	7

Performance measure: 1 = worst, 2 = neutral, 3 = best

Prima facie, the above-described conditions seem quite reasonable for engineering design practices. If one accepts the conditions, the Arrowian impossibility theorem indicates that the decision matrix methods, which aggregates the performance measures p_{ij} (i = 1, …, n; j = 1, …, m) over n options on m criteria into a global performance structure s_i (i = 1, …, n), can generate misleading conclusions by introducing significant logical errors in the decision process. This point can be illustrated by an example, which is depicted in Tables 2.1 and 2.2. Suppose that there are three conceptual designs of which only one will have to be chosen for further development. The design team has made a list of four evaluation criteria, namely production yield, process safety, controllability of the system, and economic revenues. To facilitate the choice, the design team uses the weighted-sum method (sometimes referred to as the Pahl and Beitz method) and scores the performance measure by a five-step point ranking. The resulting decision matrix is given in Table 2.1 and indicates that design concept A should be selected by the design team. Now, suppose that the team uses a three-step point rank instead, in which the concept with the best performance on a criterion receives three points, the worst scoring concept only one point and the other in-between option two points (see Table 2.2). Using the same aggregation procedure, the weighted-sum method now indicates that concept B should be selected by the design team instead. The decision procedure of point ranking in combination with weighted-sum aggregation thus gives rationally inconsistent results. In terms of Arrowian impossibility theorem, this distortion is the result of violating the 'independence of irrelevant concepts' condition. The three-point rank allows a comparison of three design concepts, while two additional concepts can be evaluated on a five-point rank. Hence, the not shown additional concepts influence the global performance structure and so violate the Arrowian condition.[8]

2.4. Information Availability

A third point of difficulty for a serious reflective debate is the presumed amount of information that is available for the selection of alternative solutions on the basis of multiple criteria in engineering design. We will discuss the uncertainties that plague engineering design work as well as the information basis of the performance measures in relation to preference and performance aggregation.

2.4.1. Design for an Uncertain Future

The selection methods aim to support the process of selecting a single or a few promising design concepts from among various alternative concepts. In order to make a decision, the performance of the designed artifact has to be evaluated. The design concepts under evaluation are only abstract embodiments of designs, which are given physical shape in detailed design and subsequent construction. The decision maker thus needs to predict the final physical form of the artifact under design. Furthermore, to evaluate the performance of this still to-be created artifact, the decision maker needs to envision the mode of the artifact's application and the effects this application will bring about. In other words, the decision process requires the prediction of future states. These predictions are made under uncertainty, which is the result of various factors: lack of knowledge (known unknowns), ignorance (unknown unknowns), system complexity, and ambiguity.

The degree of uncertainty depends on the type of design. Both Vincenti (1992) and Van Gorp (2005) make a distinction between normal and radical design. In normal design, both the operational principle and the configuration are kept similar to already implemented designs, while in radical design, the operational principle and/or configuration deviates from the convention or is unknown. In normal design, the degree of uncertainty in predicting future states is smaller compared to radical design, because in the former case, there is an effective basis of experience to base the predictions on. The degree of the uncertainty that is faced in the decision process is also dependent on the lifetime of the artifact and/or the duration of its (potential) effects. Forecasting becomes more difficult when it spans larger amounts of time. The degree of uncertainty also depends on the design phase (e.g., conceptual, preliminary, or detailed). As the design project proceeds, more information comes available and more features become defined. Moreover, the time span to the actual construction and application becomes discernibly smaller, so decreasing uncertainty. For the clarity of the debate, it is thus important that authors make explicit what degree of uncertainty the selection method is expected to incur in relation to the design type, design phase, and kind of artifact.

In the impossibility theorems for preference aggregation, as well as in the one for performance aggregation, it is assumed that adequate predictions can be made so that preferences and performance measures can be obtained without the burden of uncertainty. It is thus clear that the uncertainties, especially in conceptual phase of radical design, will complicate the selection procedure beyond the difficulties presented by the impossibility theorem. Although normal design work in the detailing phase has far fewer uncertainties about the possible future states that need to be assessed in selecting design concepts, it does not avoid the clutches of the impossibility theorem. Even in this case, the information basis is too limited for proper aggregation due to problems of measurability and comparability.

2.4.2. Measurability

In his work, Sen (1977) has pointed out that the impossibility result of Arrows theorem can be interpreted from an informational perspective. Arrow (1950) did not include the uncertainties surrounding the interpretation of future states, which are necessary for the formation of preferences. He presupposed an ideal situation in which the options of selection are known. This makes his impossibility so strong, because in practice even more difficulties will arise. Furthermore, Arrow (1950) assumes that certain information is not available as he presumes the incomparability of preferences and supposes that the measurability of preferences is restricted to ordinal scales. It is possible to relax this restriction by assuming measurements on interval or ratio scales, which would make intensity and ratio information available for the decision. The most important properties of the four fundamental measurement scales are presented in Table 2.3 (Stevens 1946).

Table 2.3: Four fundamental measurements of scale and their properties

Scale	Mathematical group structure	Admissible transformation	Example
Nominal [a]	Permutation	One-to-one substitution	Classification of data
Ordinal	Isotonic	Monotonic increasing	Mohs scale of mineral hardness
Interval [b]	General linear	Positive affine	Celsius scale of temperature
Ratio	Similarity	Scalar	Kilogram scale of weight

[a] Also refers to as a categorical scale
[b] In economics, the term ‘cardinal value scale’ is used

However, allowing for more information about preference/performance measurements on interval scales does not avoid the clutches of an Arrowian type of theorem. Kalai and Schmeidler (1977) presented a proof of an impossibility theorem that uses interval scale information; however, this proof needs an additional condition. Hylland (1980) extended the proof of Kalai and Schmeidler in such a way that the added condition is not required.

One step further is to consider ratio scale information for preference/performance measurements. However, this also seems no way out of the impossibility result, because Tsui and Weymark (1997) have shown that the theorem also holds when one allows for ratio scale measurements. Furthermore, it seems unfeasible to obtain such scales for the performance/preference measures, because design concepts are abstract embodiments that still need to be given physical form. The performance/preference measures thus refer to mental notions about what accounts for a 'good' design. The measure represents a (value) judgment, and arguably, this does not allow for ratio scale measurements. Moreover, almost no examples of ratio scale measurement exist in the behavioral sciences. Summarizing, the Arrowian type of theorem for multi-criteria concept decisions in engineering design can be extended to interval and ratio scale measurements of preferences and performances, though the impossibility result is preserved.

2.4.3. Comparability

Let us turn to the comparability part of the informational restriction. Arrow's theorem in social choice theory is set up "*to exclude interpersonal comparison of social utility either by some form of direct measurement or by comparison with other alternative social states*" (Arrow 1950, p 342). For the Arrowian impossibility theorem for multicriteria concept decisions in engineering design, this would mean that it rules out the possibility to make direct comparisons between the performances of the conceptual designs on various design criteria. In the field of social choice theory, the possibility of interpersonal comparisons has been investigated. Hammond (1976) has shown that there are some possible aggregation methods when the information basis is limited to ordinal scale comparability, even when using stronger forms of the Pareto principle and non-dictatorship conditions plus an additional separability condition. D'Aspremont and Gevers (1977) have proved the feasibility of aggregation with interval scales and unit comparability. Deschamps and Gevers (1978) have developed this further for cases of full comparability. Roberts (1980) showed that there are even more possible aggregation methods when allowing for ratio scale comparability, under the conditions of Arrow's impossibility theorem.

The mutual effects of comparability and measurements scales on the feasibility of aggregation are presented in Table 2.4. It thus becomes clear that if Arrow's theorem is relaxed in such a way that it allows for more preference/performance information in the form of comparability, there are admissible aggregation methods. However, the comparability of preference as well as performance measures is not straightforward.[9] Comparability means that there is a relationship between the various measurement scales for preferences or performances. For example, assume that the strength of the product, the speed of production, and needed investment cost are used as performance measures that account for a 'good' design. The strength of the used product cannot be lowered under a certain level regardless of the possible gains in production speed or reduction in investment cost, because the design will certainly fail and be of no value. This results in a weak form of comparability, because trade-offs can only be made within a limited range.[10] So, to escape the impossibility result, all the windows of comparability should match, which would be the exception rather than the rule in engineering design.

There is still a more pressing argument against the comparability of preference/performance measures in engineering design practice. The reality of modern engineering design is that engineers are increasingly required to factor in value-laden criteria (e.g., safety, sustainability, and reliability) into their decision-making process as early as the conceptual design phase. By their very nature, some moral values are considered incomparable. These moral values, which are precluded from trade-offs, are called protected or sacred values (Baron and Spranca 1997; Tetlock 2003), and the inclusion of such value-laden measures will make comparison between them next to impossible. All things considered, it is in principle possible to avoid the kind of difficulties associated with Arrow's theorem by using comparable preference/performance measures; however, it is our opinion that it would be very exceptional to find that all considered measures are comparable in engineering design practice.

Table 2.4: Aggregation of preference/performance structures into a global preference/performance structure in accordance with the Arrowian conditions depending on measurability and comparability

Information basis	**Scales of measure**		
	Ordinal scale	**Interval scale**	**Ratio scale**
Incomparable	Impossible (Arrow 1950)	Impossible (Hylland 1980)	Impossible [a] (Tsui and Weymark 1997)
Comparable [b]	Feasible (Hammond 1976)	Feasible [c] (Deschamps and Gevers 1978)	Feasible (Roberts 1980)

[a] A feasibility result follows if only nonnegative or positive preference/performance measures are used
[b] The notion of comparability varies with the choice of measurement scales
[c] See d'Aspremont and Gevers (1977) for proof of feasibility result under unit comparability instead of full comparability

The current discussion would be improved if authors are explicit about the information basis that they assume to be available. This can be illustrated by the seemingly contradictory opinions of Hazelrigg (1999), Franssen (2005) and Keeney (2009). Keeney claims that the "*Arrow's impossibility theorem has been misinterpreted by many*" (Keeney 2009, p 14) and he explicitly mentions Hazelrigg and Franssen as examples. However, this is not a case of misinterpretation, but of different assumptions about the information basis. Keeney provides a framework, very similar to that of Arrow's theorem, in which the preferences are expressed as von Neumann–Morgenstern expected utilities. In this framework, interpersonal comparability of these preferences is assumed, because "*the group expected utility U_j of an alternative is calculated using the individual's expected utilities U_{jk}*" (Keeney 2009, p 14). In contrast, Hazelrigg and Franssen do not explicitly deviate from the original comparability assumption of Arrow and thus exclude interpersonal comparability.

2.5. Conclusions

In order to achieve the reflective debate Reich (2010) envisioned in his editorial, it is necessary that authors are explicit about their personal goals as well as methodological aims in terms of coherence and/or correspondence (Katsikopoulos 2009, 2012). We have presented here several additional issues that cloud the current debate. First of all, difficulties in the debate result from the fact that Arrow's impossibility theorem can affect the decision making in engineering design in two distinct ways: (a) it impedes methods to aggregate preferences and (b) obstructs ways to combine various performance criteria. Secondly, misconceptions are caused sometimes by an unclear translation of Arrow's original impossibility theorem to the aggregation problem of design performances. In order to resolve this ambiguity, we have presented the Arrowian kind of impossibility theorem for performance aggregation. Thirdly, clarity is also required about the uncertainties associated with the predictability of future states in engineering design decisions, which are dependent on the considered (a) kind of designed artifact, (b) type of design, and (c) design phase. Finally, the debate would be clarified, if the assumed information basis for the decision is made explicit, especially with regard to comparability and measurability. We think the explicit consideration of all these issues will go a long way to come to a truly reflective debate on decision-making methods for engineering design.

Endnotes

[1] Coherence refers to the internal consistency of the decision-making process (e.g., the method contains no logical contradictions), while correspondence refers to the external consistency (e.g., success of the made decision in the real world).

[2] The earlier Pugh's controlled conversion method (Pugh 1991, 1996) is mainly a tool to enhance design creativity. Several others have adapted the method into a selection tool by calculating net scores (Ulrich and Eppinger 2008) or overall ratings (Eggert 2005). These Pugh-like methods are also known as Pugh's concept selection methods.

[3] The impossibility result does not hold in the situation that there are only two alternatives to choose from; see for example May's theorem.

[4] A single preference ordering refers to the set of ordinal measures between different options, while the collective preference ordering refers to the aggregated single preference orderings over these same options.

[5] The theorem is formulated in such a way that it is consistent with all three fundamental measures of scale as discussed in Sect. 2.4.2. The original theorem of Arrow, as presented in Sect. 2.2, is restricted to ordinal measures of preference.

[6] A performance structure refers to the set of relations between different design concepts. The global performance structure (e.g., the scores on the three alternative concepts in Table 2.2) is the resulting set of aggregated relations of the performance structures on the various criteria (e.g., the ranks on the three alternative concepts on the four criteria in Table 2.2).

[7] In a more formal sense, reflexivity means that for all a that are an element of set A, it holds that aRa, with R representing a binary relation on set A (e.g., a is greater than or equal to a). Transitivity means that for all a, b, and c that are an element of set A, it holds that aRb and bRc imply aRc (e.g., a is equal to b and b is equal to c, implying that a is equal to c). The asymmetric part of R is the binary relation P defined by aPb that is equivalent to aRb and not bRa. The symmetric part of R is the relation I defined by aIb that is equivalent to aRb and bRa. In social choice theory, the relation is normally taken as binary; nonetheless, the binariness of choice is unimportant for the impossibility result of Arrow's theorem (see Sen 1986).

[8] It should be noted that the point ranking as used in the example can, at best, be interpreted as ordinal scale measures. If the point ranks are measured on an ordinal scale (see Sect. 2.4.2), the

weighted-sum method gives meaningless scores, because it uses an inapplicable arithmetic operation (addition of performance measures) to calculate the scores of the global performance.

[9] Even if one allows for interpersonal comparability, it is not obvious that the analogon in inter-criteria comparability also holds. In interpersonal comparisons, preferences could be compared with respect to the same value (e.g., human welfare), whereas design criteria may relate to different values.

[10] To make performance measures more 'comparable', mathematical normalization procedures are sometimes applied. However, such normalization only shifts the comparability issue away from the aggregation method toward the normalization procedure and hence does not resolve the comparability issue.

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Chapter 3

RC: Everything will be unquantifiable.

K: You have to come down on one side or the other. I need a decision.

RC: It's not a decision, it's a guess. It's like flipping a coin and asking me to decide whether it will be heads or tails.

K: And?

Robert Capa & Kaneda – Sunshine

Chapter 3: Usage and Evaluation of Decision Matrices - Innovative Conceptual Design

Abstract

Decision matrix methods for engineering design are proposed as tools to select between various design concepts on the basis of a number of criteria. In an empirical study on innovative conceptual process designs in (bio)chemical engineering, it was found that the investigated design engineers frequently apply decision matrices. However, they did not use the matrices as a decision-making tool or as a justification for their choices. Rather, our study suggests that designers use matrices to support the selection and judgment formation process. Matrices are helpful in structuring the design problem, initiating creativity, and facilitating communication. Therefore, we argue that decision matrices should be evaluated on the basis of pragmatic criteria rather than on the basis of coherence or correspondence criteria.

3.1. Introduction

Designers make many decisions under limited information. Information is lacking in particular in the conceptual design phase of engineering design, and when innovative technologies are involved. In the conceptual design phase, alternative design concepts (abstract embodiments of a design) are generated, evaluated, and selected for further development. The goal of the concept selection is to reduce the amount of alternative design concepts to a single concept or a few promising concepts, which will be developed further in subsequent phases of the design process. It is generally accepted that concept selection, made in the initial design phase, has a large impact on the success of the final product or process (Dieter and Schmidt 2009).

To select the 'best' design alternative(s) for subsequent development the design team engages in several decision-making activities. In general, the choice is based on various criteria that are linked to the design specification and requirements generated in consultation with the customer and producer. Concept selection resembles multi-criteria choice, in which one or several options are chosen from a list of alternatives on the basis of a number of criteria. Various methods to support this concept selection have been developed, including decision matrices, feasibility judgments, heuristic decision rules, pair-wise comparisons, product profiles, and prototype testing (Dieter and Schmidt 2009; Roozenburg and Eekels 1995; Ulrich and Eppinger 2008).

Decision matrices are widely used in engineering design practice (Carucci 2010; Lopez-Mesa and Byland 2011). In the engineering design literature, there is a long-standing discussion about the methodological rigor of these decision matrices. It is argued by some authors that these methods suffer from a few disturbing methodological problems, that in principle could impact the concept selection process negatively, while other authors refute these claims (see Katsikopoulos 2009; Reich 2010; Jacobs et al. 2014). In the debate it is generally assumed that the decision matrices are "*methods for making decisions*" (Katsikopoulos 2012, p084504-1). However, in the ethnographic account of Bucciarelli (1996) it is suggested that these methods also help to develop 'shared meaning'. In this paper we look at the use of decision matrices in engineering design practice empirically and we answer the question: how do design engineers in (bio)chemical engineering use decision matrix methods in practice in the case of innovative design projects? To answers this question, we have empirically investigated how engineers use decision matrices in six different conceptual design projects in the fields of chemical and biochemical engineering. In this paper we present a critical inquiry based on the results of our empirical studies.

This paper is structured as follows. Firstly, we describe the decision matrix methods. Secondly, we explain the used research methods and describe the subjects of our empirical studies. Subsequently, we argue on basis of our findings that the decision matrices are not used as a selection tool. In the following sections, we will show that the studied designers use decision matrices to provide insight, to stimulate creativity, and to facilitate communication. Finally, we suggest that pragmatic criteria of evaluation are better suited to investigate the rigor of decision matrix methods, as they are actually used in innovative engineering design.

3.2. Decision Matrix Method

In the conceptual design phase, design concepts are evaluated with respect to various criteria, comparing their strengths as well as weaknesses, and one or more concepts are selected for further development. Various kinds of decision matrix methods are applied in the selection procedure. The weighted-sum method (WSM), sometimes referred to as the Pahl & Beitz method (Pahl and Beitz 2005), is just one of the numerous variations on this typical construction of a decision matrix. Analytic hierarchy process (AHP), Pugh's controlled convergence method (PCCM), quality function deployment (QFD), and weighted-product method (WPM) are some examples of the variations on the typical construction (Akao 2004; Hauser and Clausing 1988; Pugh 1996; Saaty 1980).

Table 3.1: Typical construction of the decision matrix

Criteria	Weight	Concept $_1$	Concept $_2$	…	Concept $_n$
Criterion $_1$	Weight $_1$	Performance $_{11}$	Performance $_{21}$	…	Performance $_{n1}$
Criterion $_2$	Weight $_2$	Performance $_{12}$	Performance $_{22}$	…	Performance $_{n2}$
…	…	…	…	…	…
Criterion $_m$	Weight $_m$	Performance $_{1m}$	Performance $_{2m}$	…	Performance $_{nm}$
Global performance	- -	*Score $_1$*	*Score $_2$*	…	*Score $_n$*

All matrix methods use a similar basic structure and they result in a table[1] in which design concepts are compared on the basis of criteria. Here we understand the typical decision matrix as a table consisting of the performance measures on various criteria of the design concepts under consideration (see table 3.1). Each concept is listed in a column of the matrix, and the criteria are placed in consecutive rows. Criteria for selection can come from various sources, such as customer needs, requirements of the producer, distributor's wants, and legal standards.

Depending on the specific method, weights are assigned to the various criteria to indicate the difference in importance between the criteria. There are several systematic methods that can be followed to determine weighing factors, for example direct assignment, objective trees, and weight criteria setting as in the analytic hierarchy process. When concepts, criteria, and weights are listed, the design concepts are subsequently measured on their ability to meet a given criterion by denoting the specific performances measure.[2] The performance structure on a criterion can be expressed in a variety of ways; the simplest and mostly used approach is the assigning of ranks. Finally, the performance measures are translated into a global score with the use of an aggregation method. The score of the design concept denotes the global performance structure and on the basis of these scores the most preferred concept can be selected.

3.3. Study and Method

3.3.1. Study Subject

To investigate how selection matrices are used in actual practice, we have carried out an empirical study of six conceptual design projects in the fields of chemical and biochemical engineering. The studied engineering designs are innovative capstone projects that are given as a course at Delft University of Technology. Each design project has a study load of 15 ECTS-credits for the Master of Science students (MSc); while the course is more intense for the postgraduate trainees pursuing a Professional Doctorate in Engineering (PDEng) with a worth of 17 credits (see table 3.2). The reason to choose capstone design projects was threefold: these projects are (a) accessible, (b) resemble industrial design projects, and (c) allow for intensive observational techniques.

Table 3.2: Six different design projects investigated in this study

Design team	Level of course	Number of team members	Duration of the project	Field of engineering
A	MSc	5	13 weeks	Biochemical
B	MSc	5	12 weeks	Chemical/biochemical
C	MSc	5	14 weeks	Chemical/biochemical
D	PDEng	3	30 weeks	Biochemcial
E	PDEng	2	18 weeks	Biochemical
F	PDEng	4	22 weeks	Biochemical

The aim of the capstone design projects is to design a system for an industrial client with a new concept or technology and to evaluate its technical as well as its economic feasibility. The teaching goal is to offer a realistic experience with conceptual process design, to generate design alternatives, interdisciplinary group work, integration of engineering know-how, and project management. The designers are required to do their group work mostly independently under the supervision of a design coach (supervisors), and assistance by instructors and engineers (advisors) can be requested.

Engineers from industry (the client), who have an interest in an innovative engineering design that can be implemented within the firm, propose the topic of design and commissions the projects. Each design project is done for a different client and the topics range from design of 'methane production with carbon dioxide valorisation' to the design of 'flexible pharmaceutical particulate production process'. Clients for the design projects include industrial partners from consortia and/or individual companies such as DSM and Schering-Plough. The studied projects from which we draw our observations are thus authentic design proposals of various industrial clients and, hence, were made under confidential disclosure agreements. To protect this confidentiality, technical details will only be given if needed for the argumentation.

3.3.2. Study Methodology

Our empirical study was conducted by three complementary qualitative research methods during the running of the design projects. The use of multiple qualitative methods makes it possible to study the topic from various perspectives as well as to triangulate evidence (Ball and Ormerod 2000). First of all, the design teams were studied during their work and meetings using quasi-participant observation techniques. Field observations were made by direct observation and data collection was done by means of field notes together with supplementary notes detailing the observer's comments and reading of events. To reduce undue influence; the investigator presented himself as an engineer among engineers (Van Gorp 2005), observation periods were not planned, the investigator had no influence on the evaluation of the work, and it was agreed to keep the names of the participants confidential. During the design work, the investigator assumed the role of interested engineering colleague without contributing directly to the design work; during meetings, the role of listener was adopted.

In addition to quasi-participant observation, design documents were analysed. Also, concluding interviews (semi-structured) were held with the design team, advisors, and supervisors after the design was finished. Documents for the qualitative analysis consisted of the intermediate digital documents and materials that the designers shared via network drives, as well as the project reports developed by the design team. The semi-structured interviews were held after the conceptual design was finalised and the committee of engineers (consisting of supervisors, industrial client and some advisors) had graded the capstone design project. Data from the various interviews were collected by means of taking interview notes. In the group interview with the design team, the preliminary results of the observation were presented to provide a new perspective as well as to correct observations if needed. Separately, informal and semi-structured interviews were held with advisors and supervisors of the design course.

3.4. Discussion of Results

3.4.1. The Matrix Methods in Practice

The practical application of decision matrices in innovative conceptual engineering design was investigated in an empirical study of six design projects. It was found that all design teams used decision matrices in the initial stages of the design process (see table 3.3). The designers initiated the use of decision matrix methods and we observed that the supervisors, as well as the advisors, accepted and stimulated the use of these methods. The design teams used different types of matrix methods, which were all based on methods described in the literature. However, the procedures stipulated in the method were not applied strictly, but used as a guide, from which could be deviated if and when desired. These observations seem to be in line with those of López-Mesa and Bylund (2011), who found that automotive designers used their own methods that resembled decision matrix methods from academic literature, or resembled modified existing decision methods. Furthermore, the authors noted that the designers did not accurately follow every step of the procedure, if existing methods were used (López-Mesa and Bylund 2011). This loose way of using the decision matrix is also observed in our study. In the concluding interviews, the designers and supervisors indicated that the decision matrix was used correctly and it found the matrix a "*useful tool*" for the design project. The supervisors thus sanctioned the loose use of decision matrices.

3.4.2. Prescriptive Use

During the process of making a conceptual design, we observed that the designers within the design teams already had a good notion of which design concept they preferred for further detailed design, before they constructed a decision matrix. This observation indicates that the matrix method was not used to prescribe the selection.

Table 3.3: The practical implementation of the reported decision matrix by the six studied design teams

Design team	Performance measure	Aggregation	Weighting
A	Data & Symbolical	No	No
B	Numerical	Yes	Yes
C	Numerical	Yes	Yes
D	Symbolical	Yes	No
E	Numerical	Yes	Yes
F	Numerical	Yes	Yes

Other observations corroborate that decision matrices were not used for prescriptive purposes. First of all, various design concepts that were considered during the use of creativity methods were discarded before a decision matrix was made, because these concepts were deemed unsuitable or unfeasible. Some designers called this "*doing a reality check*". One coached referred to "*looking for show-stoppers*" as a way to reject design concepts before constructing the matrix. So design concepts were dropped without the use of the decision matrix, because the design team had already made a pre-selection.

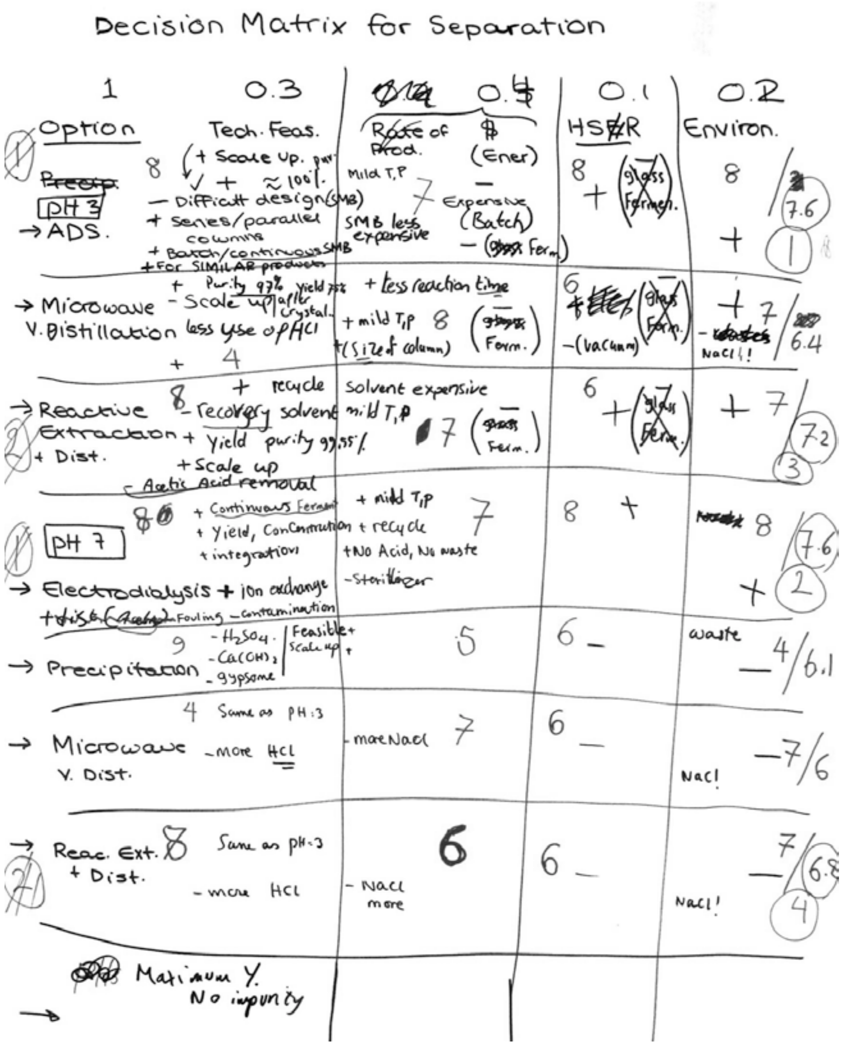

Figure 3.1: Photo of flip-over utilised for construction of the decision matrix in which the design team made extensive alterations.

Furthermore, we observed that 3 of the 6 design teams concluded that some criteria are missing or weights are wrongly assigned, if the decision matrix didn't indicate their preferred design as the best option. The criteria, weights, and performances were then reconsidered in the hope that the already preferred concept would come out on top. This is not to imply that design teams cheated their preferred concept into winning; however, it does indicate that design teams had already made the decision without the aid of the decision tool and that they had trouble making this choice explicit within the matrix method. These difficulties with constructing a decision matrix are visible in figure 3.1. Design team C initially made level ranks (black +/- symbols) with textual explanations that resulted in a global preference order (green encircled numeral at the left hand side). Thereafter, performance measures were altered into point ranks (red numerals) and weighting factors (black numerals on top) were set. The numerals were altered, as indicated by the scratched away parts and overwritten numbers, before these were aggregated into a score per design option (green encircled numeral in red at the right hand side) and given a new preference order (green encircled numeral at the right hand side). Furthermore, the environment was made a separate criterion, which was firstly part of the health, safety, environment, and risk (HSER) criterion.

Figure 3.1 also illustrates another way in which the design team had already a preference among the design concepts separate from the global performance structure. The seemingly two most promising options both received the same score of 7.6. Even though both design alternative received the same final score and had the same performance measures for all criteria, the design team was still able to conclude that the 'ph 3' design (first option in figure 3.1) was to be preferred over the 'ph 7' alternative (fourth option from the top). Arguments to support the choice were presented in the text of the report and were discussed on merit with the client in meetings. This observation is a further indication that the design team struggled to make their selection explicit in the decision matrix. Furthermore, it indicates that the design team already had a preferred design concept, independently from the aggregated scores in the decision matrix.

Thirdly, we observed that in 3 of 6 cases the matrices contained the 'traditional' design that already is used commercially or patented by other manufacturers. Since the goal of the conceptual design work is to make an innovative design, it is clear that the 'traditional' design will not be chosen over the other design concepts and it serves only as a kind of reference point or datum. For example, in the design projects about an innovative way to produce bio-fuel manufacture, the production of biodiesel from animal manure was compared to the existing production of diesel from crude oil. Hence, some concepts that were listed in the matrix were already determined not-to-be selected, even though they may be expected to perform very well. The intentionally adding of not-to-be selected concept(s) ones again indicates that the design teams did not use the matrix prescriptively.

The final observation that indicates that design teams did not use the matrices prescriptively is that the design teams did not always select the design that is indicated as 'best' by the matrix method. In one instance, a design team selected a design concept that came out second, because in a meeting the designers and the client came to the agreement that the 'winning' concept was not preferred. Moreover, another design team did not even use an aggregating rule (see table 3.3) to translate the performances on the various criteria in one global performance structure to compare the various design concepts. Hence, the team made the judgment without having the scores in the matrix to indicate the selection via the method.

Contrary to the expectation that a selection tool would prescribe the choice the designers make by giving a global preference structure, the decision matrix was in our study not used to prescribe a selection.

3.4.3. Descriptive Use

Another possible use - besides the prescriptive use - of decision matrices is to document the decision making of the designers so it can serve as a record in later design stages. We call this the 'descriptive use' of the matrix. However, we observed that the design teams did not revise this matrix for documentation after the decision was made, as one would expect, if the matrices were used descriptively. In the design project, in which the team selected the concept that came out second, we observed that the unmodified matrix ended up in the appendix of the final report, still highlighting the concept that was not chosen. Hence, the design team saw no need to update the matrix, because it had served its purpose in its 'incomplete' form. In general, we observed that when new information was acquired during later phases of the design, such as in the detailing phase, the matrix was not updated and the decision is not revised. It should be noted that most of the studied designers did change the contents of the constructed matrix during the initial phases of the design process when new information was obtained. However, we observed that this altering of the matrix stopped at the moment an 'acceptable' decision was made in consent with the client and the supervisors. So in three cases, the constructed decision matrix did not reflect the final decision.

This observed practice might seem dubious since one could imagine that when radically new information comes available in the later phases of the design that would make the selected design concept infeasible. However, it turns out that in the cases studied no tremendously discrediting information was found after the decision moment. Rather, it was observed that designers tended to create the minimally necessary conditions such that the selected concept stays within the anticipated performance. For instance, in three cases when the design teams learned that the chosen concept appeared not to be as inherently safe as was expected during the decision making, they added additional safety measures to the design, such as safety barriers or procedural guidelines, in order to increase the safety level towards the previously expected level. In other words, the designers changed the details of the design concept without altering the basis of the concept in such a way that it didn't warrant a revision of the decision. It thus seems that the revising of the decision is considered more costly than making modifications at a more detailed level of design. In interviews it was confirmed that the design team considered it "*too late*" to change the selection, because "*the project needs to be finished in time*". Hence, our study indicates that in engineering practice the matrix methods are abandoned, and no longer revised after an agreement has been reached on the selection of a design concept for detailed design work. This also explains why decision matrices were mostly put in the appendix of the final report and were not updated with new information obtained after the decision had been made.

It is thus clear from the above that in our study the decision matrices were not used descriptively, because they did not describe how the studied designers actually made the decision nor did they always reflect the final decision made.

3.4.4. Structuring the Problem

In practice, design matrices are neither used prescriptively nor descriptively. Still they do provide insight in the factors that affect the decision, and they force the design team to make their decisions more explicit. Consider the following observation we made. The design team A had proposed to select one of the considered concepts and had communicated this to the client in a short memo. The client did not approve of the selected concept and a complicated communication by e-mail ensued. At the next design meeting, the issue was still not resolved. However, during the discussion of the decision matrix, it became apparent that the design team had not considered a company-specific design requirement that the client had held implicitly. When this surfaced, the issue was quickly resolved and an alternative concept was selected for further detailed design. In this case, the decision matrix forced the designers to order the information in such a way that it became apparent that they had neglected certain customer requirements.

We also observed that the matrix provides the design team the ability to focus on problematic areas. For example, design team A identified that a particular design concept had 'good' performances on most criteria, but was lacking on one criterion. This prompted the design teams to put efforts in finding a solution to boost the performance on the underperforming criterion. The 'traditional' design (see section 3.4.2) was used in these cases as a benchmark as to what should be at least achieved to get a design concept that measures 'well' against all measured criteria.

The decision matrix likewise helped the design teams to get back to the bigger picture of the design work. In the design process, team member took up separate tasks and worked these out. We observed that teams came together after working on their specific task separately and combined the results in a draft version of the decision matrix. After discussing the overall goals of the design project, tasks were distributed, based on problem areas or missing performance measures. In a way, the team members all work on a part of the design problem and put the pieces of the puzzle together in the design matrix.

After ample work to get the best performances out of design concepts, we observed that design teams recognised that no single choice existed that performs best on all the criteria simultaneously. Therefore, the designers had to find compromises that balanced conflicting criteria. We observed that three of the six design teams used weighting factors to resolve the trade-offs within the decision matrix. In one case, the supervisor actively suggested the design team to use weighing factors to indicate how they compared the value of the used criteria. This use of the matrix provides insight into the trade-offs that need to be made and makes this part of the judgment formation more explicit. Hence, the use of decision methods gave greater understanding by structuring trade-offs between criteria, various considered design concepts, performance of these concepts, and diversity between them.

3.4.5. Creativity

In various cases, the additional insight provided by the matrix helped the design teams to develop new design concepts. As discussed, the decision matrix made it possible for the design team to focus efforts on weak points in the conceptual design. We observed that several design teams took additional time to do a creativity session. For example, design team A used brainstorming, in order to develop ideas to improve the design concept with respect to an underperforming criterion. The ideas from these creativity sessions could, in the end, not directly be implemented in the existing design concept. Therefore, a new design concept was created and added to the decision matrix.

We observed also another way in which the decision matrix enhanced creativity. Several design teams tried to combine various concepts to reduce weak performances. Most of these efforts did not result in improvements of the existing design concepts, but some of them generated novel design concepts. In one case, the design team had a design concept that performed well on almost all criteria except for the selectivity to the final product. Among the other considered design concept, one had a very high performance on the selectivity criteria. In an effort to improve the lacking performance measure the team tried to combine the two concepts together. It turned out that direct combination was not straightforward, because the changes in the reactor would also affect the downstream processing of the design and required other trade-offs. In the end, a new design concept was constructed that had its own performance structure on the design criteria considered.

To conclude: the matrix method can play a practical role in stimulating creativity in engineering design practice by presenting the information in such a way that it inspires improvements and novelty.

3.4.6. Communication

Besides structuring the factors affecting the decision, and generating new design concepts, the decision matrix also facilitated communication. All design teams in our empirical study used the matrix in the initial phase of the design project in reports, meetings, and presentations. The decision matrix is a clear visual tool that improved communication between the various parties involved (client, supervisors, and designers) by creating a kind of common language. In the concluding interviews, all parties expressed that this aspect is greatly valued, because it removed ambiguities that are the result of everyone's personal representation of the design process at the start of a design project.

An observation that illustrates how decision matrices played a role in communication is the observation that three of the six design teams also entered criteria in the matrix that were solely used to distinguish concepts from each other rather than being performance measures for a 'good' design. These 'criteria' were entered in the matrix to indicate differences among the various design concepts; however, these differences were not related to design specifications, legal requirements, or requirements of the client. In other words, these 'criteria' did not reflect properties that indicate how 'well' the designs were expected to perform; instead they only highlighted dissimilarity between design concepts without being relevant for the selection. For example, the design team E used the decision matrix to make a selection between various conceptual reactor designs. One of the criteria used by the design team was the hydraulic retention time. The design team discovered that this retention time was mentioned frequently in the engineering literature, because it shows a major difference between the reactor types under consideration, even though in this specific case the hydraulic retention time had, at best, a marginal indirect effect on the desired specifications and requirement. So some criteria are added to show the dissimilarity between the design concepts to other people involved in the project.

As already described in section 3.3.1, we observed that the decision matrix also contained design concepts that were already excluded from selection. These design concepts were placed in the matrix by the design team to benchmark the innovative concepts on their performance. It showed the client and supervisors on which points the selected design concept was superior to the benchmark. In other words, the decision matrix was used as a way to communicate that the created design was at least as 'good' or even 'better' than the benchmark.

The decision matrix thus facilitated the presentation of the information in such way that a decision could be made that was 'acceptable' to all parties involved in the design. Hence, the visual character of the matrix had a function in the communication during the design process.

3.5. Implications

Our observations make clear that in the investigated projects the decision matrix is not used as a prescriptive tool. It also became apparent that the decision matrix is not used descriptively, i.e. to describe how the decision was made. Rather, in the conceptual design phase, the decision matrix method was used to support judgment formation by:

- facilitating communication about the choice to be made,
- revealing further insight in factors influencing the decision, and
- stimulating design creativity.

3.5.1. Evaluation Standards

Our findings on the practical use of decision matrix methods in engineering design practice impacts the current debate about the validity of decision methods in engineering design. We argue here that the evaluation of the method should consider its practical use as well. Method evaluation can be based on various standards that stem from different philosophical theories of truth (Schmitt 2004). According to Hammond (1996), decision methods can be evaluated according to standards based on coherence and/or correspondence. Dunwoody (2009) has advocated extending these two types of evaluation standards by also including pragmatic standards that are based on usefulness.[3] Katsikopoulos (2009, 2012) has investigated the current debate about the validity of decision methods in engineering design and concluded that the authors in the debate use distinct ways to evaluate the validity of decision methods based on achieving coherence and/or correspondence.[4]

The assessment standards for a coherence type of method evaluation will examine whether the decision process meets the test of consistency. The coherence standards ask whether the method is consistent with other existing rules, such as logic and mathematics. In contrast, evaluation based on correspondence would focus on assessing the predictive ability of the method. Correspondence standard for assessment inquire how well a method provides results that are in line with the empirical facts. It is, however, unclear how this criterion can be translated to a decision method. We cannot compare the results of the method with the given facts, i.e. the actions taken and the consequences of these actions. The aim of a design work is, after all, to change the world and not to conform to the existing state of affairs. One possible interpretation might be to judge the method on how many times it gives a selection that needs to be revised. However, this supposes that we can judge that a decision needs to be revised independently from the decision method itself, which is contestable. Finally, the assessment standards grounded in a pragmatic account of truth will ask whether the method is practically useful. A pragmatic standard focuses, for example, on the added value of the method with respect to the user and then tests the method's usefulness for the user in performing its intended function. It thus asks, if the decision method supports the decision making by the designer.

Coherence standards for the evaluation of the decision methods are useful in the sense that they can be evaluated before the method's application and can identify logical inconsistencies. However, these are ill suited for the practical uses of the decision matrices as described in section 3.3. Correspondence standards are well suited for evaluating the predictive and descriptive functions of a method (Dunwoody 2009). However, we have found that in practice the decision matrices are neither used prescriptively nor descriptively. The matrix method's practical uses in conceptual designing, such as facilitating communication, providing insight, inspiring creativity, are internal to the engineering design team and not to the method itself. Pragmatic standards are well suited, because pragmatic assessment primarily focuses on goal obtainment. To do justice to the rich variety of uses that matrix methods have in engineering practice, we propose to employ pragmatic standards of evaluation. Nonetheless, these pragmatic evaluations are very context-dependent. Therefore, no far-reaching conclusions can be made on the basis of such standards and reassessment is advised when the method is used in a different setting.

3.5.2. Limitations of this Study

Even though this study indicates the practical use of the decision matrix methods, it does not shed light on how engineers exactly justify their design decisions. Our empirical study shows that decision matrices were used to aid the judgment formation process rather than as decision-making tool. This also means that they do not have a justificatory function with respect to the decision made, as is often supposed in literature on these methods. It raises the question how engineers then justify their design decisions and what role, if any, the decision matrices do play or can play in such justification. The answer to this question is also important for the further development of decision-aiding tools, because ideally one would want that such tools are not only assessed as 'useful' by the designers, but also result in better justified decisions. Here, apart from pragmatic standards, coherence and correspondence standards seem relevant. However, as far as we know, remarkably few studies have been conducted that assess how engineers justify their design decisions.

Our empirical study has focused on the conceptual design phase. The conclusions from this study are, therefore, not directly applicable to other phases of the engineering design process. Further study into the use of decision matrices methods in other phases of the design process, such as detailed engineering design work or to the retrofitting existing technological artefacts, could supplement this work, and give a more complete overview.

This study also focused on innovative design work in the engineering field of (bio)chemistry. It would be of interest to investigate, if the findings of this study are confirmed in other fields of engineering. This could be done by studying the use of matrix methods in capstone design projects of other faculties, such as civil engineering, mechanical engineering, or architecture. It also seems reasonable to expect that various specific kinds of matrix methods would be useful in different phases of the design process and fields of engineering. Additional research would be useful to pinpoint practical requirements for the further development of specifically tailored decision methods.

Endnotes

[1] The typical table of the decision matrix method, has been given various names in literature as well as in practice such as: design matrix, decision table, evaluation matrix, problem chart, problem-solution matrix, selection table, selection grid, or solution table.

[2] These performances are not mere physicals properties of the design concept, such as height or weight. The performance of a design concept on given criterion is a mental notion on what account for a 'good' design. The measure is thus a (moral) judgment, defined by the expected application of the product/process under design.

[3] There are various other theories of truth such as deflationary, discursive, and performative theories. Nonetheless, the three best known as well as mostly frequently discussed theories of truth, which we use here, are sufficient for the current discussion.

[4] Katsikopoulos interprets coherence as "*internal consistency*" and correspondence as "*external performance*" or "*success in the real world*".

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Chapter 4

The first rule of being a good engineer is that it's not about the stuff you build.

It's about the people who use it.

Mitchell Hundred – Tag

Chapter 4: The Fire and Explosion Index in Innovative Engineering Design - Methodological and Application Issues

Abstract

Innovative engineering design requires judgements about safety issues. Tools that provide a measure of the safety performance of design concepts can support such judgments. In an empirical study, we explored how designers in biotechnology and chemical technology use the Dow's Fire and Explosion Index (F&EI) as a performance measure in their capstone design projects. Our findings suggest that the F&EI in its current form is not a practical measure of safety in the early phases of conceptual innovative design, because (a) the F&EI does not support the formation of design judgment in the early phases of the design process, (b) the result of the F&EI does not provide a representative measure of safety in innovative design, and (c) the F&EI is not compatible with the underdetermined and contextual nature of conceptual design work. It is recommended that a tool is built to support judgement formation about safety in the early phases on conceptual design, and the F&EI could be a good basis for such a new tool.

4.1. Introduction

Safety has become an important factor in the process industry, especially to avoid severe accidents that might damage public acceptance. Inherent safety (Kletz 1991) is a generally recognised and proactive strategy for incorporating safety considerations in process design. The aim of this strategy is to create an inherently safer design by eliminating process hazards instead of adding protective barriers. In the early phases of conceptual design, there is leverage to select and generate alternative design options that can lead to inherently safer designs. In order to do so, designers need to recognise potential hazards of design alternatives. Various methods are available to evaluate process safety, including Concept Hazard Analysis, Dow's Chemical Exposure Index, Dow's Fire and Explosion Index, Failure Mode and Effects Analysis, Fault Tree Analysis, Hazard and Operability Study, and Mond Fire Explosion and Toxicity Index (Tixier 2002 and references therein). In this chapter, we will focus on Dow's Fire and Explosion Index.

Inevitably, the designer has to make trade-offs during the design with respect to safety, since significant reductions of one hazard may increase other hazards, hamper operability, or weaken the economic feasibility of the production process (Hendershot 1997). In order to select the 'best' design alternative, the designers need, what we call, *design judgement*. During the formation of such judgement, the designers can be aided by assessment tools that provide performance measures of the designed process on specific criteria, such as safety and economics. The Dow's Fire and Explosion

Index (F&EI) can be used to this end. It is a widely used safety assessment tool (Khan 2003) and can be applied to compare design alternatives on safety performance (Ramirez 2011; Suardin 2007).

Engineers use performance measures to assess the attainment of specifications and requirements with respect to alternative design options. A useful method should therefore support the judgment formation needed for such selection. This judgement can be supported by allowing direct comparisons between alternatives, inspiring alterations on existing design concepts, and communicating hazards with all stakeholders. Another desired aspect is that the performance measure provided by the F&EI should be constructed in such a way that its inputs are appropriately used to generate an output, in order to prevent incoherent and illogical outcomes. A proper method should also be usable in the context for which it is applied. In this case we will evaluate the compatibility with innovative design practice. Taken together, a useful method should: (a) support judgment formation, (b) provide a representative measure of safety, and (c) be compatibility with innovative design practice.

The question we will address in this chapter is whether the F&EI gives an useful performance measure of safety that can support design judgement in innovative engineering design. This question mainly seeks to evaluate the F&EI based on the practical application of the method by engineers in design projects. We will answer the research question by critically enquiry into the three mentioned aspects. Our analysis is based on empirical evidence from direct observations of innovate design projects taught at our own university.

The chapter is organized in the following manner. The next section provides details about the case selection, case subject, and the qualitative research methods used for our empirical study. Sequentially, the methodology and practical application of the F&EI are described. The following three sections present our findings on the usefulness of the F&EI as a measure of performance in the capstone design projects. The usefulness is explored by investigating in which way the F&EI support judgement formation, provides a representative measure of safety and its compatibility with engineering design practice. Finally, conclusions will be drawn and suggestions are provided for further research.

4.2. Research

4.2.1. Case Selection

We investigated six different innovative capstone design projects that were given as a course at Delft University of Technology in the field of biochemical engineering. These capstone design projects were selected for the following reasons: (a) they were easily accessible, (b) had a high similarity to industrial design projects, (c) provided opportunity for intensive observational techniques needed for the study, and (d) were similar enough for making comparisons. Similarity among the cases was obtained by selecting design projects that had similar attributes (see table 4.1). The educational set-up of the studied design projects were monitored to be similar, despite differences in instructors and clients. The design projects all aimed at an innovative design proposal that was worked out on a conceptual level. Therefore, all these projects were characterised by a high level of uncertainty and ambiguity.

4.2.2. Capstone Design Project

Capstone design courses have become a regular component in nearly every discipline of engineering education. These senior-level design projects have been developed with the aim of providing an experimental learning activity in which the knowledge gained from mathematics, natural science, and engineering science courses is combined in a final hands-on project. The development of these design courses is primarily stimulated by industry and educators, who expresses the need for graduates that are better prepared for engineering practice on the job (Dutson 1997; Dym 2005). The place of these capstone design projects in the engineering curriculum is further strengthened by the requirements set by accreditation agencies, such as the Accreditation Board for Engineering and Technology (ABET), the Institution of Chemical Engineers (IChemE), and the European Network for Accreditation of Engineering Education (ENAEE), that require design practice to be incorporated in engineering curricula. For example, the ABET explicitly states that within the engineering curriculum "[s]*tudents must be prepared for engineering practice through a curriculum culminating in a major design experience based on the knowledge and skills acquired in earlier course work and incorporating appropriate engineering standards and multiple realistic constraints*" (ABET 2010).

Table 4.1: Characterisation of the variety of capstone design projects in engineering education based on eleven attributes. The indicated scope of the attribute gives an indication of the range of possibilities. The final row represents the characterisation of the projects that were investigated for this chapter

Attribute	Scope			This study
Educational format	Structured class	-	Independent work	Self-active with coaching
Course duration	One quadmester	-	Several semesters	420-476 hours/student
Student work	Individual	-	Student team	Team of 2-5 students
Student background	Single discipline	-	Mixed disciplines	(Bio)chemical engineering
Designed artefact	Process	-	Product	Conceptual process
Design case	Authentic	-	Simulated	Provided by industrial client
Final output	Hardware	-	Paper report	Detailed design report
Evaluation basis	Formal exam	-	Final output	Report and presentation
Provided guidance	Single supervisor	-	Team of instructors	Panel of instructors
Client of the design	Real user	-	Imitated role	Industrial partner
Industrial involvement	None	-	Liaison engineer	Client of the design

In the literature, various examples of empirical studies on capstone design projects given at various universities can be found (Auzenne 2006; Downey and Lucena 2003). Sheppard and Jenison (1996) propose a two-dimensional framework for characterising engineering courses, including capstone design projects. One of the two axes is based on the 'what' (analysis to strategy development), while the second axe is based on the 'who' (team-based to individual-based). The framework is very helpful to broadly categorise courses in engineering education, although it is not very finely grained. Dutson et al. (1997) highlight four differentiating aspects of capstone design courses, knowingly (a) duration of the design process, (b) structure of the format, (c) course content, and (d) criteria for evaluation. Building on these aspects and the typology of Sheppard and Jenison (1996), in combination with our own experiences, we propose to characterise the capstone design projects based upon eleven attributes (see table 4.1). The proposed eleven-point characterisation is especially constructed for capstone design projects, but could be extended to incorporate other design related courses, such as reverse engineering or dissection courses.

In our empirical study, we investigated six capstone design projects at Delft University of Technology in the field of biochemical engineering. Three of these projects were completed by teams of five graduate students that are pursuing a Master of Science (MSc) degree in biochemical or chemical technology. Teams of two to four postgraduate trainees doing a Professional Doctorate in Engineering (PDEng) carried out the other three investigated projects. The design projects have a course load of 15 and 17 European Credit Transfer and Accumulation System (ECTS) credits for the MSc students and PDEng trainees respectively.

The format of the course is based on independent work on the given design project with assistance by instructors, consisting of faculty staff, and coaching by engineering design specialists, from faculty or industry. The goal of the design project is to provide students with a realistic experience in innovative conceptual process design work in which a high degree of integration of engineering know-how is achieved. The course thus aims to provide experience with teamwork, creating design alternatives, project management, and communication skills. To complete the course, the team has to show that it can transform their creativity and knowledge into an integrated, innovative, and consistent conceptual design that satisfy the needs and requirements of the client.

The design projects are commissioned by clients who have a vested interest in an innovative process design as part of an on-going research and development program within their firm. As such, the design project is not artificial or simulated, but rather a real project done for an industrial client, and it requires meeting industrial standards. Topics of the design project range from the design of 'a flexible pharmaceutical particulate production process' to the design of 'a system that produces biogas from organic waste'. Clients for the design projects include industrial partners from companies such as DSM, Friesland Foods, and Schering-Plough. The design projects were made under confidentially agreements. As a consequence, the chapter will only give technical details, if strictly needed for the argument made.

The capstone projects result in a conceptual design, with a focus on process design. The conceptual design includes the generation of design alternatives, process selection, selection of unit operations, performance assessment, basic design of process equipment, overall process control, economic evaluation, as well as the assessment of safety, health, and environmental impacts. The generated conceptual design has to be presented and defended before a committee of engineers, which includes faculty staff as well as the client. The design projects are divided into two major parts, which are both finalised with a written report and an oral presentation. The first phase, leading to the Basis of Design (BoD), took roughly one third of the whole project time. In the BoD, the design team presented their preliminary conceptual design for review in a formal meeting with the client and instructors. The BoD should cover all key data and assumptions for the design as agreed with the client, such as economics, battery limits, feedstock, products, and plant location. Furthermore, the BoD should include basic block schemes of unit operations for the possible process alternatives, justification of the process selection, and planning for the next phase. The Detailed Design (DD) phase was the second part of the project and spanned the remaining two thirds of the allocated time. In this phase, the conceptual design was elaborated in more detail by adding economic ratios, equipment sizing, mass & heat balances, process conditions, process flow schemes, process stream summary, process control review, and a safety study. The committee of engineers graded the work on the design project as a whole.

4.2.3. Research Methods

The empirical material was obtained by qualitative research, because these research methods are well suited to investigate (a) the way F&EI is used in practice, (b) the motivation behind application of the F&EI, and (c) the impact of the F&EI results on the final design. Furthermore, qualitative methods are also suitable to study how the F&EI is used as a performance measure in the formation of design judgement (Ball and Ormerod 2000). A great amount of tacit knowledge is involved in judgement formation, which can be investigated by such methods (Lopez-Mesa and Bylund 2011). In the empirical study, we used three complementary qualitative research methods, knowingly observations, interviews, and document analysis. The use of different research methods does not only provide alternative perspectives on the topic of study, but it also makes it possible to triangulate evidence (Ball and Ormerod 2000; Yin 2009) to check results for consistency.

Throughout the *observations*, the investigator presented himself as an engineer among engineers to indicate that he was able to understand the 'language' of engineering (Van Gorp 2005). In this way, influence on the design process was reduced, because the designers, instructors, and industrial client did not feel compelled to simplify or water down explanations. Furthermore, it provided a more casual atmosphere in which the observer was just one additional member of the group with an interest in the project. We agreed to keep the names of the participating designers, instructors, and industrial partner confidential in order to strengthen this atmosphere of openness. The exact identity of those involved is not strictly needed for the arguments presented in this chapter.

To further avoid undue influence on design practice, this study used quasi-participant observation techniques, instead of full-participant or non-participant observation methods. Designers in training are more easily influenced in their design behaviour than senior engineers and as such full-participation could result in undue influence. Non-participant observation techniques could lead to uncomfortable situation, because the observer remains isolated and is seen as someone who is watching every move and scrutinising every (potential) mistake. Therefore, we used the quasi-participant observation method in which the observer assumes several roles, which are made clear to the group. In our investigations, the observer primarily took the role of interested engineering colleague, without contributing directly to the design work. The role of listener was assumed during the design meetings as well as during conferences with instructors. At the final interview, the role of investigator was assumed. It was also made clear to the design team that we would not take the role of advisor or instructor and so had no influence on the grade received at the end of the course. Field observations were made by direct observation in the natural setting and data collection was done by means of field notes. The observational data was supplemented with notes detailing the observer's comments and reading of events. Observation periods were casual and not planned, except for the formal meetings and presentations with instructors and client, which were arranged by the design team.

Qualitative *document analysis* and semi-structured interviews were used complementary to the quasi-participant observations. Documents for the qualitative analysis were obtained from two different sources. We had access to intermediate digital documents and materials that the design team shared via network drives. Furthermore, the two major reports developed by the design team, knowingly the BoD report and DD report, were obtained for analysis. The semi-structured *interviews* were held with the design team after the conceptual design was finalised and the committee of engineers (consisting of instructors, industrial client and some advisors) had graded the capstone design project. In this group interview, the preliminary results of the design project were presented and the participants were asked if the results represented the reality of what had happened. In doing so, the semi-structured interview presented a new perspective on the design project by letting the designers reflect on there own work. In addition, the semi-structured interview served as a regulating method, because it allows for the triangulation of evidence from the three qualitative research methods. Separate informal and semi-structured interviews on a one-to-one basis were held with instructors of the design project course to obtain their view on the preliminary results. Data from the various interviews were collected by means of taking interview notes.

4.3. The Dow's Fire and Explosion Index

In this section we will provide a description of an F&EI method and its application in the studies capstone design projects. The subsequent sections we will investigate the F&EI on three aspects of usefulness, before drawing conclusions in the final section.

4.3.1. The Methodology

The Dow Chemical Company originally developed the F&EI in the mid-1960s. The F&EI guide has since been published by the American Institute of Chemical Engineers (AIChE 1994) and is widely used as simple screening tool to quantify the potential damage of fire, explosion (Khan 2003), and reactivity incidents by identifying equipment units contributing to potential accidents, and by ranking them relatively. Furthermore, the F&EI can be used in communications with management about potential risks (Scheffler 1994), though this communication function seems to be less widely acknowledged. The F&EI is a qualitative and deterministic approach that generates a hierarchisation of operations on safety (Tixier 2002). The approach provides an index number (1 to about 300) that classifies the operational units into five hazard rankings (light, moderate, intermediate, heavy, or severe). This index number can be used to target efforts for improving safety towards the most hazardous parts of the process.

Fire & Explosion Index	
1. Material	
A. Hydrogen	21
B. Carbon monoxide	21
C. Ethanol	16
D. Water	1
Material Factor (MF)	*21*
2. General Process Hazards	
Base Factor	1.00
A. Exothermic Chemical Reactions	0.00
B. Endothermic Processes	0.00
C. Material Handling and Transfer	0.00
D. Enclosed or Indoor Process Units	0.00
E. Acces	0.20
F. Drainage and Spill Control	0.25
General Process Hazards Factor (F1)	*1.45*
3. Special Process Hazards	
Base Factor	1.00
A. Toxic Material(s)	0.40
B. Sub-Atmosferic Pressure (< 500 mm Hg)	0.00
C. Operation In or Near Flammable Range	
1. Tank Farms Storage Flammable Liquids	0.00
2. Process Upset or Purge Failure	0.00
3. Always in Flammable Range	0.80
D. Dust Explosion	0.00
E. Pressure	0.50
F. Low Temperature	0.00
G. Quantity of Flammable Material:	
1. Liquids or Gases in Process	2.00
2. Liquids or Gases in Storage	
3. Combustible Solids in Storage, Dust in Process	
H. Corrosion and Erosion	0.10
I. Leakage - Joints and Packing	0.10
J. Use of Fired Equipment	0.00
K. Hot Oil Heat Exchange System	0.00
L. Rotating Equipment	0.00
Special Process Hazards Factor (F2)	*4.90*
Fire and Explosion Index (F1 x F2 x MF = F&EI)	**149**

Figure 4.1: Example of a completed Dow's fire and explosion index sheet, indicated as a 'heavy degree of hazard' posed by the process unit analysed.

The determination of the F&EI number is done in a step-by-step approach based on the F&EI sheet, of which an example is presented in figure 4.1. The F&EI is calculated as the product of a material factor (MF), general process hazard factor (F1), and special process hazard factor (F2). The MF is a value based on flammability, instability, and reactivity of the most hazardous substance in the process unit. The value can be obtained from various databases, the material safety data sheet, or manual calculation using point scale of the 'fire diamond' from the National Fire Protection Association (NFPA). The F1 is calculated as the sum of all the penalty factors given by the designer for aspects that determine the potential magnitude of an accident, such as exothermic or endothermic reactions, material management, spill control, and unit confinement. The F2 is calculated similarly, though it also contains the aspects for the probability of an incident, including elevated or reduced pressures, corrosion, joint leakage, operational temperatures, and use of fire heaters. In addition to the degree of hazard, other risk information can be obtained with the use of the F&EI Hazard Classification Guide, such as the maximum probable property damage and potential business interruption times.

4.3.2. Application in Capstone Design Projects

In making an innovative process design, the design team needs to take into account safety considerations to design an acceptably safe process, despite of the potential hazards involved. In the studied capstone design projects, the design teams were required to take safety aspects into consideration from a process design perspective, with an emphasis on reducing the safety risks for operating personnel. The course manual suggests the use of the F&EI to 'quantify' these safety aspects by filling in the F&EI sheet and calculating the index number.

We observed that the design teams in the studied capstone design projects indeed selected the F&EI as a tool to assess the safety of their design, because they were urged to do so. We witnessed several occasions in which an instructor relayed to the design team that the F&EI is a compulsory element of the DD report. The design team used the F&EI in response to such requests and answered to our interview questions that the F&EI "*just had to be done*". The data from the participant observations suggest that the designers see the pressing request to calculate the F&EI made in the manual as well as by the instructors as a kind of test of skill, akin to an exam question. The design teams in our study were not required to do the complete assessment as presented in the guide, and all teams stopped the assessment when the index number and related degree of hazard was obtained.

4.4. Supporting Judgement Formation

4.4.1. Concept Selection

In order to investigate the use of the F&EI in forming design judgments, we firstly focus on the selection of alternative design concepts in the BoD phase of the project. If the F&EI would play a role in judgement formations it should be applied to inform the selection made. However, it was observed that four out of the six design teams chose to make the F&EI near the end of the design process, see table 4.2. These four design teams already scheduled the use of the safety tools in the last few weeks at the start of their project and the faculty instructors, as well as the client, approved this time planning. This timing suggests that the design teams did not intend to use F&EI as a performance measure for their designs, because the late application makes it impossible to use the F&EI index for the selection of design concepts for further detailed design.

We observed that the overall schedule was hard to keep in practice, due to unforeseen circumstances or overly optimistic estimates of the time needed. Under this time pressure, teams needed to reschedule and set priorities. In all cases, the F&EI was further postponed, and given less time than scheduled initially. We observed that this, in some cases, led to a situation in which a single team member made the F&EI the day before handing in the DD report. Furthermore, the text in the manual supports the late application of the F&EI by stating that it should be "*carried out on the final conceptual process design*", implying that the design is already completed, or at least nearing completion.

Table 4.2: Use of the Dow's Fire and Explosion Index by the six design teams, indicating in which phase of the design the index was made, what was analysed with the index, and the resulting degree of hazard

Design group	Timing	Scale of analysis	Degree of hazard
MSc 1	Last weeks of DD	Whole process	Moderate
MSc 2	Final week of DD	Two units	Intermediate to severe
MSc 3	Final week of DD	Each unit	Light to moderate
PDEng 1	Before BoD	Two units	Severe
PDEng 2	Before BoD	Single unit	Severe
PDEng 3	Last weeks of DD	Whole process	Intermediate

BoD=Basis of Design phase, DD=Detailed Design phase

Two design teams did make the F&EI before the end of the BoD phase. However, also in these two cases, the design teams did not use the results of the index for the selection of the conceptual design. The F&EI was made only for the design concept that was selected for detailed design in the next phase. Essentially, the F&EI was made after the formation of design judgement, just before handing in the BoD report. Nevertheless, this use indicates that it is possible to make the F&EI in the BoD phase. Still, we observed that the 'severe' degree of hazard (see table 4.2) that these two teams identified were not used to alter the design concept in an attempt to lower the potential fire and explosion hazards.

Although most design teams did not use the F&EI during the BoD phase, we observed that they did consider safety at the early stages of the design process. In these cases, these considerations were not made explicit in design documents except for the safety or risk criterion that was used by most design teams in a type of decision matrix for selecting the design concept (Carucci 2010; Hendershot 1997). A single team was the exception to this general trend, since they did not use safety as a criterion in the matrix, while also making the F&EI late in design process. In the interview, this team indicated that they did not foresee any unacceptably high hazards in their design concept and so did not deem it necessary to deal with safety issues in the 'earlier phases' of the design process.

Even though the design teams were aware of safety issues in the early design phases, they used the F&EI only after the design concept for the detailed design is selected. This late application seems to be undesirable, especially in the light of (a) the inherent safety philosophy that argues for assessment of safety already in the early phases of the design to eliminate the hazard proactively and (b) the quickly decreasing ability to make changes in the conceptual design at later stages of the process when more and more design decisions have become fixed.

4.4.2. Changing the Design

If the F&EI were to be applied in the design process to form a judgement about the safety of the conceptual design, one would expect that design teams take action based on the results of the analysis. However, we observed that the instructors, as well as the client, did not expect changes to be made in light of the results of the F&EI. This is most clearly illustrated by the fact that instructors and the client approved the late scheduling of the safety assessment, did not negatively comment on safety recommendations that were not implemented, and awarded the final designs with high grades. Furthermore, the manual did not promote making changes in the design according to the conclusion of the F&EI. In the design manual, it is stated that the design team is expected "*to carry out these* [safety] *assessments, draw conclusions from them, and make recommendation accordingly*". In other words, the manual relays to the team that they only need to make recommendations, and are not required to make appropriate changes to the design. The late use, without the expectation to alter the design to implement safety consideration, is highlighted even more in the manual by the statement: "[a]*lthough many times processes cannot easily be changed, measures reducing the risks should be recommended*".

We observed that two design teams, which analysed their design concept in the initial phase, concluded on the basis of the F&EI that their design implied a 'severe' degree of hazard (see table 4.2). However, these PDEng design teams did not take any steps to change their design concept, so that it would have a lower degree of hazard. The designers indicated that they did not alter their design concept, because they were convinced that the used materials (highly flammable and explosive hydrocarbon) and conditions (highly elevated pressures) that had the largest impact on the index could not to be altered as these were set in line with the wants of the client. In other words, the design team believed that since the client had set the requirements of the design and they had informed the client about the hazard with the F&EI, the hazard was the result of the client's demands. In the interview the design team noted that they were therefore not responsible for the resulting high degree of hazard. It should be noted that these two design teams put forward some recommendations to remedy the hazardous situation, such as "*careful construction of the tanks*", "*controlled decompression in an expansion tank*", or "*hire skilled technicians*". These suggestions could be typified as secondary prevention measures (layers of protection) that are normally not considered in a conceptual design, but are typically dealt with in more detailed design and development steps. Instead, in the conceptual design step the focus is on making the design inherently safe by primary prevention. It should be noted that differences in degrees of hazard between the designs are to be expected, since all teams worked on a different design with inherently different hazards.

The other four design teams, which did the F&EI late in the design process, did also not take any action to change the conceptual design based on the analysis. Foremost, this is the result of the late use of the F&EI, which leaves little to no time to make alterations that could impact the design concept. We also observed that these teams gave no recommendations based on the results of the F&EI, although the manual requires this. These designers indicated in the interviews that the determined degree of hazard and the index sheet speak for itself in indicating the factors contributing to the hazard and the ways to remedy this situation.

4.4.3. Screening of Hazards

Beside the late construction of the F&EI, and the lack of action in accordance with the results of the assessment, another manner of usage seems to be very curious in light of the primary function of the F&EI. The index is developed as a screening tool that ranks the various process units with respect to potential degree of hazard, so that the most hazardous parts of the designed process can be improved. However, half of the studied design teams did the indexing on a single equipment unit, or on all the units combined (see table 4.2), making it impossible to screen for hazardous units. It should be noted that the manual could have lead the design team astray, since the manual states that the "*index must be done for the complete CPD* [Conceptual Process Design]". This statement in the manual could be read to imply making a single F&EI for the whole design.

Two other teams just evaluated two process units that they deemed most hazardous, with the intention to give a picture of the highest degree of hazard of the whole process. In other words, these teams used their engineering know-how to select the most hazardous equipment units and did not need the F&EI for this purpose. It is thus clear that the screening function of the F&EI was not used. Rather, the design teams used the F&EI to show quantitatively how safe or dangerous the whole process is expected to be.

These observations are not very surprising in light of the teams' perception of the F&EI as an analysis that is a required part of the project. Besides, it should be noted that our empirical data do not show that the advising faculty staff disapproved of this use of the F&EI. For example, we observed that a design team, who were behind on their schedule and under time pressure, went to an instructor for advice how to proceed with the design process. The instructor told the design teams that it was satisfactory to do the F&EI for one or two 'important' unit operations.

4.4.4. Communication

Scheffler describes how the F&EI can be used in communications about potential risks (Scheffler 1994), though this usage is less widely acknowledged. What makes the FE&I especially fit for this purpose is the visual nature of the table, and the fact that the final conclusion is formulated in the form of a single degree of hazard. Indeed, if the F&EI has a function as a performance measure, it stands to reason that it is used to enhance communication surrounding the judgement formation. However, in our observations we have found no compelling evidence that would suggest that the F&EI is used for communication in design practice. First of all, we observed no discussion about the F&EI between the design team and the client. Secondly, we also observed that within the design team there was no discussion about the implications of the results of the index. The only discussions we observed about the F&EI revolved around the correctness of a team member filling in the F&EI sheet. In other words, it was about the question whether the designer strictly followed all the prescribed procedures of the F&EI guide. Furthermore, our observations suggest that the design teams assumed that the completed F&EI sheet as well as the resulting degree of hazard speaks for itself. In the presentations given by the design teams only the numerical value of the index and/or the degree of hazard were mentioned, mostly without any explanation how it was obtained or what the consequences were for the design. However, just as the answer *42* of supercomputer, Deep Thought, to the 'Ultimate Question of Life, The Universe, and Everything' (Adams 2005), the result of the F&EI does not relay any useful information without the context of the hazards and safety measures already implemented. Therefore, we conclude that the index did not enhance communication about the safety considerations, and thus played no role in judgement formation in this respect.

The observations presented in this section indicate that in our study (a) the F&EI is not used as a measure for the selection of design concepts in the BoD phase of the design, (b) the results of the F&EI are not used to adapt the design concept, (c) the F&EI is not used to screen the design concept for hazardous operations, and (d) the F&EI is not used as a communication tool for safety considerations. All in all, the F&EI did not play a role in design judgments about safety in the cases studied.

4.5. Representative Performance Measure

4.5.1. Scales of Measure

In the group interviews, most design teams voiced reservations about the F&EI. The designers considered the numbers used for many of the penalty factors very 'subjective'. One designer indicated that the penalties and results of the F&EI entail "*large uncertainties*". Another designer voiced his dislike of the seemingly limited objectiveness of the method by expressing that "*we just took penalty numbers that seemed appropriate*". Although, the F&EI Hazard Classification Guide is in many cases very clear on which penalty factors should be used - in setting the requirement in the form of 'if situation X is present than a penalty of Y should be applied' or 'a X condition receives of Y penalty' - other statements are less clear by indicating possible ranges of appropriate penalty factors or statements such as 'this generally requires a penalty of Y'. The voiced concerns seem to indicate that design teams have difficulties making explicit their estimations as well as design judgements, and with translating these into qualitative numbers for the potential hazards.

To understand the reservations of the design teams, we investigated the penalty factors and index number of the F&EI. In the F&EI sheet, the index number is calculated from the three factors (MF, F1, and F2). In order for these mathematical operations to have meaning, the information basis of the numbers needs to be consistent with regard to measurement scales. Stevens (1946) has defined four fundamental measurement scales and identified meaningful operations for each of them (see table 4.3). The nominal scale requires the smallest amount of information. Therefore, most mathematical operations are not defined on a nominal scale. Conversely, the ratio scale requires the most information, and it is mainly used for physical sciences and engineering metrics.

Table 4.3: The four fundamental measurements of scale after S.S. Stevens related to their mathematical groups structure, selected permissible operations, and clarifying examples of the measurement scale

Scale	Group structure	Meaningful operations	Example
Nominal	Permutation	Equivalence, set membership	Arbitrary label, category
Ordinal	Isotonic	Count, comparison, greater/lesser	Comparison index, rank order
Interval	General linear	Subtraction, ratio of differences	Dates, position, sea level
Ratio	Ratio similarity	Addition, multiplication, division	Age, length, weight, volume

The index number of the F&EI is calculated as the product of MF, F1, and F2. However, such a mathematical operation is only meaningful, if all three factors are measurable on a ratio scale (see table 4.3). However, the factors seem to represent ordinal scale measures at best, because they lack an absolute zero as well as any ratio similarity or general linear group structure. Take for example the MF, which is represented by a dimensionless number, with a value of 1, 4, 10, 14, 16, 21, 24, 29, or 40. The limited set of possible numerical values already indicates that the MF is used to rank the materials in an ordered set, and not to construct a ratio or interval scale. Furthermore, it seems hard to maintain that the MF is determined on a ratio scale, since the absolute zero is undefined and the ratios between various MFs are not meaningful. For example, ratio scale measures of MF would imply that acetylene (MF=40) is four times more hazardous than diesel fuel (MF=10) and exactly as hazardous as nitroglycerine (MF=40), which appears to be dubious. The MF is also not measured on an interval scale, as in that case the distances between each interval on the scale should be equivalent along the scale. This implies questionable statements, for example, the hazard difference between toluene (MF=16) and propane (MF=21) is equal to the difference between sodium (MF=24) and perchloric acid (MF=29). Therefore, the MF neither measured on a ratio scale nor on an interval scale. This implies that the used multiplication to calculate the F&EI is not well-defined and, hence, will produce meaningless results. In a similar way, it can be shown that the summation of base factors used for calculating the F1 and F2 are meaningless, because the base factors can at best be interpreted as an ordinal scale.

In the interviews, it became evident that designers did not know the scale types of Stevens (1946), and were unaware that they employed undefined mathematical calculations in the F&EI. By closer inspection of the curriculum, it became clear that the topic had received no attention. This is probably the result of the fact that almost all measures used in engineering science and science courses are physical properties that are expressed on ratio scales. The only major exception is the temperature scale in degrees Celsius or Fahrenheit that is expressed on an interval scale, but engineers have learned to readily convert these scales to the Kelvin scale of temperature, which is a ratio scale. All in all, this seems to indicate that unwittingly the design teams used undefined calculations. The use of operations that are inconsistent with scale of measurement put the validity of the F&EI results into question, because these undefined operations may introduce logical errors in the method.

4.5.2. Comparability of Index Numbers

To assess various process operations based on the index number of the F&EI, these numbers need to be comparable (Bohringer and Jochem 2007; Ebert and Welsch 2004); otherwise, we are, in a sense, comparing apples with oranges. More formally, scales of measure are comparable, if there is a similarity between the scales that allows for comparisons. Comparability thus requires that scale transformations preserve the relevant relationships between the measurement scales. However, comparability between index number of the F&EI is not clear-cut. Comparability demands that the safety performance, as indicated by the index number used, are measured on the same scale or that a relationship for comparison between the utilised scales exists that represents the trade-off between units on one scale against units on the other scale. First of all, it is difficult to see how the safety performance of the design alternative on various hazards can be measured on one and the same scale. The hazards of fire, explosion, and reactivity, as assessed by the F&EI, result in various effects, such as injuries, long-term health effect, death, and property damage. It seems very questionable that these effects can all be measured on a single scale. For example, how would one compare the hazard of one process with issues related to fire injuries to employees by leakage of flammable liquids, with the hazard of another process that has issues with a potential dust explosion that could affect the surrounding community?

Secondly, if different scales of measure are used within the F&EI method, comparability demands that there should be a relationship that describes the trade-off between scales to come to a comparable index number. However, in practice these relations can at best only describe trade-offs at a very limited range, since they are dependent on the extent of the hazard. This leads to a weak form of comparability in which the window of comparability needs to be matched to make trade-offs possible. In engineering practice, it seems almost unachievable that all considered hazard types match in the range considered for the design judgement.

Lastly, the diversity of hazards present another difficulty for trade-off between scales, because the various criteria have different underlying moral values, such as justice, social welfare, sustainability, and wellbeing. This diversity in values makes comparability even less likely, even in principle, considering that various authors hold that such moral values are protected or sacred values that are considered incomparable by their very nature (Baron and Spranca 1997; Tetlock 2003).

Interview questions about the comparability issue indicated that the designers were not aware that the index numbers could be incomparable. Some team members even responded that there should be no comparability issue, because the numerical values of the index are without dimensions or units. This response can be explained in light of the general biochemical engineering curriculum. In engineering training, comparability of numerical values is frequently associated with the dimensions, or units, of the constants and variables expressed. To compare physical properties, such as speed, engineers have learned to check the units and convert them into a single measure. It is thus routine for engineers to make measures comparable by using existing relations between the measuring scales, which could make students assume that dimensionless indexes are comparable. It should be noted that faculty staff members who took part in the capstone design projects also relayed in the interviews that they were not aware of any comparability issues with the F&EI.

4.5.3. Scope of Measure

A measure of safety performance should encompass a wide set of diverse hazards to give an appropriate representation of the safety of a conceptual design. The F&EI focuses on fire and explosion hazards. The F&EI can thus not be used as the only performance measure of the entire safety of the conceptual design. Other methods are required to asses performance on other safety aspects in biochemical process engineering, such as toxicity, environmental impact, contamination of food grade products, release of genetically modified organisms, *et cetera*.

Other authors have also indicated that toxicity plays a very limited role in the F&EI (Abedi and Shahriari 2005; Sinnott 2005). A modified version of the F&EI, known as the Mond Fire Explosion and Toxicity Index (Mond index), includes more extensive toxicity hazards assessment. This Mond index was developed by personnel of the Imperial Chemical Industries (now part of AkzoNobel) at Mond division at Runcorn, England to cover a wide range of installations used by the company. Nonetheless, the use of the Mond Index has not become as widespread as the FE&I.

In this section we have argued that (a) the F&EI uses undefined mathematical operation leading to logical errors, (b) the index numbers of the F&EI do not provide an accurate basis for comparison of assessed operations, (c) the F&EI cannot be used as the only performance measure of safety of a biochemical process design. All in all, the F&EI does not provide an appropriate measure of safety performance on the basis of which design judgment can be formed.

4.6. Compatibility with Innovative Design

4.6.1. Limited Knowledge

A performance measure should be compatible with the kind of design work done. Here we investigate the compatibility with the innovative design work with the aim to make a conceptual process design. The investigated capstone design projects are by their nature surrounded by uncertainty, because the technologies employed have not been tested on large scale and the designs are only abstract embodiments of the envisioned physical form. The uncertainties are the result of the limited knowledge under which the designers operate, ranging from unknown probabilities of certain outcomes, through complexity shrouding outcomes, to ignorance about outcomes (unknown unknowns). The use of the F&EI under this limited knowledge requires engineering judgment to determine the penalty factors as well as to interpret the results. In this light, Norman E. Scheffler, employee of The Dow Chemical Company and involved in drafting the fourth version of the F&EI guide, warned that "*common sense and good judgment must be used during the calculation and interpretation of results*" (Scheffler 1994). In engineering textbooks, similar reservations can be found about the F&EI, for example: "*judgement, based on experience with similar processes, is needed to decide the magnitude of the various factors used in the calculation of the* [Dow's fire and explosion] *index*" (Sinnott 2005). The F&EI seems thus to be usable for innovative design work, however, experience with the proper application index is required to deal with the limited knowledge available.

We observed that the design teams used the F&EI in the late phases of the design (as already described above). This practice was explained by some of the designers in response to our interview questions. The designers firstly indicated that it was not required to use the F&EI earlier. Secondly, the designers indicated that upon their inspection of the F&EI guide (AIChE 1994) it was concluded that it requires a lot of detailed design information. For example, the setting of penalty factor for 'drainage and spill control' demands knowledge about control measures such as diking, trenches, and basin capacity. In the perception of the design team, this information was only available in the later phases of the project. This indicates that the F&EI is not very useful in the initial phases of conceptual innovative design work, without making assumptions and estimates based on engineering judgement.

4.6.2. Design Context

Another issue with the compatibility of the F&EI as a performance measure is that it presupposes a specific type of infrastructural context in which the hazard occurs. The predisposition is that the designed facility will be located in a 'normal' environment, such as an industrial park, were various 'basic' resources are available, such as infrastructure, emergency response systems, and safety awareness. Due to this presupposed context the F&EI does not take into account specific considerations, for example local environmental hazards including the potential for droughts, flooding, earthquakes, tsunamis, and tornados. However, these local factors are vital for the safe design of the production process. This has become painfully clear with major industrial calamities, such as the Japanese Fukushima nuclear power plants, that were built in proximity of active fault lines.

Another example of this assumption is that the F&EI is inappropriate for developing countries, because it is based on Western industrial practice and assumes infrastructure such as training, safety awareness, availability of funds, and material availability. Gupta (1997) has suggested modifications to the F&EI that should prevent under-estimation of the hazards in developing countries by taking into account the different infrastructure in developing countries. During our observations and the interviews, it became clear that none of the designers was aware of the limitation of the index with regard to the presupposed infrastructural reality or context. It should be noted that several interviewed instructors also relayed that they were not aware of the issues of presupposed context.

It has been argued in this section that (a) the F&EI requires more information than is available in the initial phase of innovative design, and (b) the F&EI presupposes a specific infrastructure for the location of the designed facility. All in all, the F&EI seems to be lacking in compatibility with the initial phase of innovative conceptual design practice.

4.7. Conclusion

4.7.1. Measuring Safety Performance

In this study, it has been investigated whether the F&EI gives a useful performance measure of safety that can support design judgement in conceptual innovative engineering design. We have drawn arguments from direct observations on innovative capstone design projects in the field of biochemical engineering. Our findings suggest that the F&EI is not an appropriate measure of safety in the early phases of conceptual innovative design, because (a) the F&EI does not play a role in forming a design judgment, (b) the F&EI does not provide a representative measure of safety, and (c) the F&EI in not compatible with innovative design practice. We would like to note that the F&EI does not seem very robust with regard to 'black swan events' (Taleb 2007), since the quantitative measurements used in the index are based on historic data of accidents, and on experience with practical application of loss prevention practices.

The question can be raised, if the observed use of the F&EI leads to a poor consideration of safety aspects in the produced design. We observed that all the investigated design teams received above average grades for their capstone design projects and no negative comments were made by the faculty staff, coaches, or industrial client about the consideration of safety aspects. In our opinion, this indicates that the committee of engineers determined safety to be sufficiently considered by the design team. The limited use of the F&EI does not present a hurdle to consider safety aspects in design practice. Further study is needed to investigate how design judgement about safety is formed, in order to create useful tools to support innovative conceptual design work.

4.7.2. Limitations of the Study

Our arguments are drawn from direct observation of innovative design in the conceptual phase. The conclusions from this study are, therefore, not directly applicable to other phases of the engineering design process, not in the least because of the different knowledge availability. This work can be supplemented by studies into the use of F&EI in other phases of the design process, such as embodiment design and detailed design. A more comprehensive overview can be created by studies into other types of designs with less limits of available information, such as design work for retrofitting existing technological artefacts.

The observations used in this study were made in capstone design projects that are made in an educational setting. We expect little differences with actual design project in industry, because the goal is to project a realistic experience, there is adequate coaching, and the industrial client has a vested interest in the results. Nonetheless, our observations could suggest that faculty staff saw the use of the F&EI by the students as a test of the students' ability to complete the method rather than as a tool to improve the design. It would thus be very interesting to confirm in an industrial setting that the F&EI does not play a role in forming a design judgment. However, we recognise the difficulties of getting adequate access to empirical data.

This study also focused on a specific field of engineering, knowingly (bio)chemistry. It also would be of interest to investigate whether the results are confirmed in other fields of engineering. This could be done by studying similar safety indices in capstone design projects of other faculties, such as civil engineering, mechanical engineering, or architecture. It also seems reasonable to expect that safety indices can be tailored to different phases of the design process and fields of engineering. Additional research would be useful to pinpoint practical requirements for the further development of specifically tailored safety indices.

4.8. Recommendations

In order to be able to assess the inherent safety in the early stage of design, in which the general process alternatives are developed and selected, designers would benefit from tools that support them in design judgement. Such tools should provide the designers with a performance measure that has the following characteristics:

- Capture the inherent safety principles.
- Explicit consideration of safety by easy interpretable results that facilitate communication.
- Compatible with the limited information that is available in the early design phase.
- Allow for direct comparison of design alternatives.
- Well-matched with the existing judgment formation tools, such as decision matrices.
- Able to work with a wide range of technologies, materials, and operation conditions.

The study presented here shows that the F&EI does not adequately complies with all these characteristics. This is not intended as an unfair overall criticism of the F&EI, since the method was not primarily designed for all stages of design and it fulfils a useful purpose in the field of hazard identification and quantification. However, there is a need to develop a tool that helps to generate performance measures of safety in the early phases of innovative design processes. The widely accepted F&EI could serve as a starting point on which to build, but needs to be supplemented by additional tools.

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Chapter 5

Nanotechnology - the bloom is not off the rose. Because of the far-ranging claims that have been made about potential applications of nanotechnology, a number of serious concerns have been raised about how this will affect our society if realized. And what actions, if any are deemed appropriate, might be needed to mitigate these risks. This is not Massive Dynamic's concern. We create technology. How it is used is not our concern. We just own the patents.

Nina Sharp – Subject 9

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Chapter 5: Design for Values – Nanotechnology

Abstract

Applications of nanotechnology have the potential to raise fundamentally new ethical questions. Nanotechnology is an enabling technology and therefore a whole array of moral values is at stake. We investigate these values by differentiating with respect to specific applications. We will argue that in the short-term nanotechnology does not pose novel value-laden socio-technical issues, but has the potential to enhance or provide opportunities to address existing issues. We will describe three different attempts to provide a design for safety or sustainability approach, which are specific for nanotechnology. In the long-term nanotechnology does raise new ethical questions, especially with the blurring of category boundaries. Since the current debate on long-term developments is mainly technology assessment oriented in nature, we will suggest how these outcomes can be used for a more design-oriented approach.

5.1. Introduction

Nanotechnology is an intriguing technology, not in the least because of the ethical questions it evokes. Nanotechnology is the manipulation of structures at the nanometer scale (one nanometer is a billionth of a meter). This is only a rough description of what nanotechnology entails and a broader discussion on the definition will be provided in section 2.1. Much of nanotechnology is still in the laboratory phase and for that reason the term nanoscience is often more appropriate than nanotechnology. Nonetheless, some results are already on the market (first generation nanotechnology) and others are about to be realized commercially. These current applications of nanotechnology may not give rise to fundamentally new ethical questions, but the wide variety of applications and possibly far-reaching consequences have led to the situation that the design and development of nanoproducts is surrounded by social debates that are often organized and facilitated by governments. As the development of nanotechnology is influenced by a variety of aspects, nanoethics is complicated and involves knowledge from a variety of disciplines (Vries 2006, 2008). In this chapter we will analyze what kind of ethical issues are at stake with the current developments and discuss some first attempts to provide a 'Design for Values' approach specific for nanotechnology.

There are also long-term developments with possibly very important impacts that are already discussed now, in spite of the fact that speculation is involved in such debates (Grunwald 2010; Nordmann 2007). In the long-term in particular, new ethical issues seem to emerge. The new domain of synthetic biology, for instance, raises new questions about boundaries between natural and artificial, and ethical questions related to that (for instance, are natural and artificial 'life' equally worthy to protect?). Therefore, short-term and long-term developments will be discussed separately. The long-term debates often have a technology assessment oriented nature: possible effects are studied or imagined and based on the outcomes of that, a general assessment is made of whether or not we should develop such an application. In this chapter we will use literature of that kind, but also seek a more design-oriented approach in which we will ask the question what role values could and should play in the development of those applications. Of course, the outcomes of the technology assessment type of studies can be used for such design-oriented considerations as they provide clues of what is in line with certain values and what is not.

One of the interesting aspects of nanotechnology is that several authors have claimed that it raises new ethical issues (Ferrari 2010; Preston et al. 2010; McGinn 2010). It can always be debated whether or not an ethical question is truly novel or not. As we will see, nanoethics is certainly not fundamentally different from ethics in other technological domains. But particularly in the long-term expectations, we do see complications for Design for Values.[1] As Van de Poel (2008) argues, we should not only focus on seemingly new ethical issues as we may then overlook other important issues. He also makes the point that important ethical issues may only become clear during the further development of nanotechnology (Van de Poel 2008). In establishing values we often refer to certain categories that we are used to. Intuitively we divide in living versus non-living, healthy versus ill, natural versus artificial and the like, and value certain categories over others. For instance, we may opt for an ethical stance in which natural is better than artificial (e.g., in the case of food), or living things are more worthy of protecting than non-living things. Certain applications in nanotechnology tend to confuse the boundaries between such categories (Swierstra 2009; Verbeek 2009). That creates a problem when assessing values. Thus, Design for Values can become problematic, as it is not clear what values are at stake or how they relate to certain categories.

In this contribution we will give an overview of nanotechnology, before we will analyze the ethical issues that are at stake in the short and long-term development of nanotechnology. We will then give an overview on three preliminary attempts to provide a Design for Values approach that are specific for short-term nanotechnology development; we will also discuss approaches for the longer term. To provide ample context to the approaches, the ethical issues with current application of nanoparaticles in sunscreens and the long-term application of cyborgs are discussed. We will end the contribution by giving suggestions for further work as well as drawing conclusions.

5.2. Nanotechnology

Within a decade, nanotechnology has become a major technological theme across most scientific and engineering disciplines. Especially since the start of the USA-based National Nanotechnology Initiative (NNI) in 2000, nanotechnology captured the imagination of various stakeholders. Governments all over the world have launched and promoted nanotechnology programs, initiatives, and business alliances to benefit from the identified economic potential that nanotechnology promises to bring as well as to keep up with scientific and technological advances elsewhere. The almost unprecedented technological movement on a global scale has been stimulated by promises of a 'next industrial revolution' (Committee on Technology 2000). Nanotechnology thus may appear like a creation of politicians given these strong political efforts by governmental funding and stimulation. Nonetheless, products with nanosized materials as well as components are currently being designed, produced, and used. The application of nanotechnology will likely grow further as spending in nanotechnological related R&D increases (Malanowski et al. 2006; Rensselaer 2004).

5.2.1. Description of Nanotechnology

Nanotechnology works in the area between isolated molecules and larger solids, regularly referred to as the size range of 1 to 100 nm. Phenomena occur in this transient area, which are not observed on molecular nor on macroscopic objects. Nanotechnology can be used in numerous applications areas, such as agriculture, chemical industry, construction, cosmetics, energy, healthcare, information technology, textiles, and transport (Malanowski et al. 2006). Currently, nanomaterials are utilized in various commercial products already on the market, including anti-microbial wound dressings, anti-fog layers, food packaging, chemical catalysts, multimedia data recorders, cosmetics, LED-based lighting, diode lasers, low-friction coatings, microelectronics, and sunscreens. The Project on Emerging Nanotechnologies of the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts keeps an inventory of manufacturer-identified nanotechnology-based consumer products currently on the market.[2] As from the start of 2011 the inventory holds more than a thousand entries in very diverse categories.

The very large and diverse array of applications as well as its enabling nature suggests that the term nanotechnology is more an abstraction than a clearly defined field of technology (Davis 2007). Nanotechnology is not so much an industry, nor is it a basic technology in the classical sense with a clearly defined field. Nanotechnology is a collection of tools and approaches that can be adopted for specific applications. Nanotechnology is called an 'enabling technology', since it can be applied to drive developments in derivative technologies in diverse fields.

Nevertheless, the term is widely used as a kind or shorthand representation of product and processes that utilize nanoscale properties. There is currently no widely accepted definition of nanotechnology (Balogh 2010). The lack of agreement on a definition that is shared by all stakeholders (including manufacturers, regulators, enforcement bodies, and consumers) has proved to be challenging, because it forms a hurdle in developing policies and setting up proper regulations (Romig et al. 2007). In comparing the definitions proposed by various authors it becomes clear that nanotechnology refers to at least three considerations:

- The dimension in the nanoscale range.
- Properties or phenomena that can be attributed to this dimension.
- Intentional exploitation of these properties or phenomena.

Here we will use a working definition closely related to the broad definition provided by the Royal Society (Royal Society & Royal Academy of Engineering 2004) that entails these three common considerations. We define nanotechnology as design, production, and application of structures, devices, and systems by controlling shape and size with a least one critical dimension in the order of 1 to 100 nm. In this respect nanomaterials are intentionally engineered with at least one critical dimension in the order of 1 to 100 nm for a specific property. We refer to nanoparticles when we mean nanomaterials of specific shapes, such as dots, bars, dendrimers, colloids, tubes, and wires.

Nanomaterials possess properties different from their constitute materials of molecular or macroscopic size, because several physical phenomena become more pronounced at the nanoscale. These pronounced properties can be the result of quantum effects that play a more dominant role in the nanosize range compared to larger objects or they can result from the highly different physical properties, such as increased surface area per unit of substance compared to macroscopic systems. For example, titanium dioxide powder is known for its white appearance, while nanosized titanium dioxide is transparent. Furthermore, it should be noted that the 1 to 100 nm size range is in the order of magnitude at which many biological systems operate. These properties of nanomaterials enable applications, which are not possible using molecular or macroscopically sized materials. To reach the nanolevel there are two basic approaches in nanotechnology. In the 'bottom-up' approach materials and devices are constructed from molecular components, essentially by building nanomaterials atom by atom. For this approach molecular self-assembly is very important. The 'top-down' approach is the refinement of techniques and practices to the point that they reach the nanolevel and in essence the nanomaterial is constructed by breaking down larger objects.

5.2.2. Short History of Nanotechnology

Nanotechnology is a relatively recent development and its roots are frequently associated with the presentation of the famous physicist Richard Feynman gave at Caltech in 1959 entitled 'There's Plenty of Room at the Bottom' (Feynman 1960). Even though Feynman did not use the term nanotechnology and his talk did not receive much attention until the beginning of the 1990s (Toumey 2009), it is considered inspirational to the field of nanotechnology. In fact, it was Norio Taniguchi of Tokyo University of Science who first coined the term 'nano-technology' at a conference in 1974 (Taniguchi 1974). The term got popularized by Kim Eric Drexler in his book 'Engines of Creation: The Coming Era of Nanotechnology' published in 1986 and got well known in the scientific community once the journal 'Nanotechnology' was founded in 1989.

The most well-known nanomaterials are fullerenes, such as the buckyballs and carbon nanotubes. Sir Harold Walter Kroto, Richard Errett Smalley, and Robert Floyd Curl, who share the Nobel Prize in Chemistry for this breakthrough, discovered buckminsterfullerene in 1985. The discovery of carbon nanotubes is attributed to Sumio Iijima in 1991, although Roger Bacon at Union Carbide and Russian scientists behind the Iron Curtain were already working on such carbon fibers in the 1950s and 1960s (Colbert and Smalley 2002). From a more technical perspective, the field of nanotechnology started to develop in the 1980s with the invention of the scanning tunneling microscope and the atomic force microscope. The advances in microscopy are vividly illustrated by the Don Eigler and Erhard Schweizer paper in Nature of 1990 that reported that they had spelled out the name 'IBM' with 35 xenon atoms.

The event that got the field off the ground was the huge scale National Nanotechnology Initiative (NNI) project of the United States in 2000. The U.S. commitment to nanotechnological development is significant with a the cumulative governmental funding up to 2010 in the order of 12 billion US dollar, which makes it only rivalled by the NASA space program. The market size of nanotechnology-enabled products is estimated at about 250 billion US dollars worldwide. Development analysis projects that the number of nanotechnology products will achieve a 3 trillion US dollar market and 6 million workers by 2020 (Roco 2010).

Together with the first conception of nanotechnology in the mid 1980s there was mention of the possible ethical, legal, and ethical implications (ELSI). When large-scale organizations emerged to promote research and development of nanotechnology in the late 1990s – such as the Foresight Institute, the US National Nanotechnology Initiative, and the EU nanotechnology program – funding of accompanying research in ELSI as well as environmental, health and safety (EHS) of nanotechnology became the norm. The first major attempt to evaluate the social and ethical implications the nanotechnology development was a workshop of the National Science Foundation in 2000. The most influential report on the possible implications of nanotechnology was put forward by the Royal Society and Royal Academy of Engineering (2004). The possible negative effects of nanotechnology were popularized by many end-of-the-world scenarios. For example the grey goo of out-off-control self-replicating robots that consume all matter on the Earth in the novel 'Engines of Creation' by Drexler, or the swarm of sentient nanorobots in the novel 'Prey' by Michael Crichton.

5.2.3. Central Moral Values and Values Issues

As indicated in the introduction, most of the moral values and related moral issues at stake with nanotechnology are not fundamentally new nor are they unique to nanotechnology. For example, Kuiken (2010) has argued that "[t]*he ethical issues surrounding nanomedicine* […] *are not new, but rather the techniques and science to achieve these improvements are new*". This is not to say that the concerns raised by these moral issues can be dismissed as 'nothing new'. Novelty of a moral issue in general seems to be a poor guide for allocation of ethical inquiry. We would rather argue that, although the novel moral issues seem philosophically more interesting, the non-unique moral issues also deserve attention. Since nanotechnology is an enabling technology, it can intensify these existing non-unique moral issues or provide ways to address these issues. Furthermore, the application of nanotechnology could result into situations in which moral values are combined in new ways, come into conflict in unprecedented manners, or require a reconsideration of the perception of the moral value at stake, due to the altered context of the situation brought about by nanotechnology.

Nanotechnology is an enabling technology and therefore whole arrays of moral values are at stake. The moral issues arise from the integration of nanotechnology with the socio-technical context in which it is emerging. Hence, the nanomaterial by itself does not have an obvious recognizable connection with application and can only be used in a limited way to identify value issues. A more promising route is to address the moral values from the perspective of nanotechnological applications. With a perspective on applications it is more straightforward to investigate relevant impacts and therefore reflect on the value issues at stake. In other words, the values, which are at stake in nanotechnology, are dependent on the context of its application. For example, carbon nanotubes are being utilized in displays, probes for atomic force microscopes, sensors, as well as lightweight composites for bikes, boats, windmills, and space travel. All these applications give raise to different moral issues with specific emphasis on particular moral values. In accordance, we will thus differentiate the moral values with regard to the specific applications.

To provide further structure to our analysis we will distinguish between short-term and long-term applications of nanotechnology. With short-term applications we mean the applications of nanotechnology, which are currently on the market or have high promise to reach market in the near future. Examples of current applications of nanotechnology are silver nanoparticles as anti-odor agent in textiles, and titanium dioxide nanoparticles as UV filters in sunscreens. In contrast, long-term applications are envisioned utilizations of nanotechnology in the far future. In the short-term an important role will be played by moral values such as equity, justice, privacy, responsibility, safety, and sustainability, while in the long-term the focus will be on other values such as human dignity, integrity of human nature, and intergenerational justice.

Our analysis does not address moral issues that can arise during the process of research related to nanoscience. Examples are safety issues with regard to the use of nanoparticles within the laboratory and accountability issues with authorship of publications. The focus is on the moral issues of the applications of nanotechnology in the context of the product life-cycle as well as the way designers, engineers, and developers are able to shape the nanotechnology enabled product with respect to the moral issues at stake during its life-cycle.

5.2.3.1. Values in the Short-Term

Various authors have already investigated the moral values that play a central role in applications of nanotechnology (Choi 2003; Lewenstein 2005; Malsch and Hvidtfelt-Nielsen 2010; Sandler 2009; Royal Society & Royal Academy of Engineering 2004). The most frequently mentioned moral values associated with nanotechnology provided by these authors are: accountability, animal welfare, autonomy, fairness, equity, justice, nonmaleficence, privacy, quality of life, responsibility, safety, security, sustainability, transparency, and user friendliness.

Of these moral values, accountability, fairness, equity, justice, nonmaleficence, and responsibility are related to the power distribution and social interactions that shape the co-existence of technology and society. Since nanotechnology is an enabling technology the socio-technical issues related to these values are legion and span a very wide range. The issues include, for example, lack of accountability in industrial as well as military research, unequal access to specific health care treatments, and externalization of environmental costs of manufacturing methods (Sandler 2009). Nanotechnology is not the cause of these problems, in the sense that it is not the cause of the socio-technical issue, because the issue was inherent in the technology that is enabled by nanotechnology as well as the technology's social embedding. Nevertheless, the introduction of nanotechnology in the socio-technical context can intensify the existing problems due to the distinctive properties and functionalities that nanotechnology can provide. The flip side is that these features of nanotechnology can also provide opportunities to contribute in addressing the socio-technical issues. For example, currently there is an uneven utilization of technology at the international level, which leads to issues of equity. As nanotechnology enables existing technologies, it seems likely that countries having a high utilization of technology will benefit the most of the development of nanotechnology, which would lead to an exacerbation of the inequalities. This concern has been termed the 'nano-divide' and concerns have been raised about further uneven power and wealth distribution.

Table 5.1: Selection of short-term application of nanotechnology with their most prominent moral value(s) at stake in the current debate.

Technological sector	Application	Key moral value
Agricultural	Cattle monitoring	Animal welfare
	Product identification tags	Security, Privacy
	Nutrient delivery	Safety
	Shelf-life enhancing packaging	Transparency, Safety
Chemical industry	Reaction catalysis	Sustainability
Construction	Barnacle resistant coatings	Sustainability
	Self-cleaning surfaces	User friendliness
	Weather resistant adhesives	Sustainability
Cosmetics	Anti-odor creams and sprays	Safety
	UV filter for sunscreens	Transparency, Safety
Energy	Foldable solar cells	Sustainability
	Improved energy storage	Sustainability
Health care	Anti-microbial agent	Safety
	Diagnostic sensors	Privacy, Safety
	Drug delivery	Safety, Quality of life
	Surgical implants	Autonomy, Quality of life
Information technology	Energy efficient displays	Sustainability
	Information storage	Privacy, Security
Textiles	Anti-odor	Safety
	Chemical protection	Security
	Water-resistance	User friendliness
Transport	Fuel additive to increase efficiency	Sustainability
	Light weight materials	Sustainability

The other moral values, which are not directly related the above described socio-technical issues, such as animal welfare, autonomy, privacy, quality of life, safety, security, sustainability, transparency, and user friendliness are highly dependent on the specific application that nanotechnology enables. Table 5.1 gives an impression of the sort of moral values that are at stake here. This table is based on an extensive literature study of which the most important references can be found at the end of this chapter. No effort was made to make a systematic inventory; Table 5.1 shows the variety of values only, not a precise distribution of values over topics. For example, privacy is a key value at stake in ICT applications using nanotechnology for storing personal information, while it is of a very limited importance with deodorants that utilize nanomaterials as active ingredient.

5.2.3.2. Values in the Long-Term

Ethical enquiries into the long-term developments of nanotechnology commonly revolve around the manipulation of individual atoms and molecules that would lead to the ability to build any desired construction, ranging from nanoartifacts at the nanoscale to artifacts at micro- and macro-level. The one-by-one atom construction of larger artifacts would, of course in theory, require a very long time, as billions of atoms need to be placed in position. To solve this problem, the idea of general assemblers has been developed. These assemblers are in concept very similar to ribosomes in nature. They serve as machines that first multiply themselves and their exponentially growing 'offspring' builds the artifact. An animation called nanofactory was published on Youtube to illustrate how a laptop computer could be built that way.[3] This development is still very speculative; nevertheless in the ethical debate it is assumed that it makes sense to reflect on this development, because if it would be realized it would have great consequences and many moral values would be at stake.

The primary domain of ethical concern seems to be that of medical technologies. The most far-reaching expectations of long-term nanotechnology developments are that it will be possible to repair human tissue so that life can be prolonged almost at will. This would have a great impact on human beings, as now one of its perhaps most important characteristics is its mortality.[4] Transhumanists welcome this development, but the question can be raised if humans will be able to make sense of life if it lasts for maybe hundreds of years. This permanent change in human potential is an example of what is called 'human enhancement' (Lin and Allhoff 2008). Rather than restoring health in a situation of illness, human enhancement aims at enhancing human capabilities, both physical and mental. An issue at stake here is the possibility of a social divide: those who can afford to be enhanced may get control over others.[5]

Another development that would have a great impact on the nature of human existence is the possibility of making direct connections between the human brain and a computer. It is already possible to make a direct connection between nerve cells and devices for seeing/hearing and even an electrical wheelchair. Nonetheless, connecting the brain to a computer and thus being able to 'read' what is in our mind would raise ethical question about the integrity of our human existence. Furthermore, the ability not only to manipulate the human body but also to have detailed knowledge about its state by means of complete DNA analyses using lab-on-chip devices could have as a consequence that we will be judged by our DNA. Already now, we see objections when insurance companies use medical data to determine the insurance rates one has to pay. Many would probably see being judged by one's DNA as a degradation of human dignity.[6]

The possibility of a new asbestos problem that was already mentioned in the previous section, becomes more pressing when the long-term development of nanotechnology would lead to the possibility of creating extremely small devices that can invade the human body, e.g. in the veins to open obstructed arteries. If complete control of such devices is not guaranteed, they may get lost in the body and cause unpredictable damage. The same holds for nanodrugs that have a special coating that dissolves only at places where there are certain chemical substances that indicate the presence of a diseased cell. What will happen to the coating once it has dissolved? Do we know for sure it will not harm? Here, the value of safety is at stake.

5.3. Approaches in Designing for Values

As in the previous section, we will make a distinction between short-term and long-term. For the short-term Design for Values approaches, we focus on available approaches which deal with designs of nanotechnological utilizations that have high promise to reach market in the near future, giving special empahasis towards the moral values identified in section 5.2.3.1. For the long-term we look at approaches that cope with envisioned applications of nanotechnology in the distant future.

5.3.1. Short-Term Approaches

Nanotechnology is one of the first technological developments in which funding agencies -like the National Nanotechnology Initiative (NNI) in the USA, the Framework Programs of the EU, and NanoNed in the Netherlands - required accompanying ethical (ELSI – Ethical, Legal, and Social Issues - and EHS – Environment, Health and Safety) research. Most of these efforts are directed at specific parts of EHS research, such as nanotoxicity, mobility of nanoscale materials, and workplace practice. In ELSI the focus is mainly on regulatory capacity, outreach, and public acceptance. Other efforts in ELSI research that accompanies nanotechnological R&D that involve moral issues are mainly aimed at the engagement of the public with developments in nanotechnology. So these efforts primarily focus on communicating with the general public and involving public opinion in policy setting. Hence, they can offer a forum for debate on ethical issues of nanotechnology, though they do not directly strive to develop approaches to Design for Values.

Overall, it is not an overstatement to say that within the ELSI research into responsible development of nanotechnology the perspective of design has received little attention. Approaches to Design for Values that are specific to nanotechnology are missing, due to this limited scholarly effort into this field. It should be noted that the current funding focus on ELSI research aimed at engagement studies is not so surprising after the backlash in the field of biotechnology with genetic modification and the general association of ethics in relation to technology with prohibitions and restraints. This association is most commonly expressed in the sense that ethical issues should be addressed to prevent negative effects on the development and implementation of the technology. In essence, a proscriptive role[7] is assigned to ethical inquiry. However, we would like to stress that moral values can also be used in a positive sense. In other words, moral values can be used to encourage and guide the 'good' development of technology, which requires one to identifying what is desirable and worth of pursuing as individual and for society.

As described in section 5.2.3 there is a whole range of moral values at stake in the application of nanotechnology. However, only a few authors have described approaches in which these values could be used in a positive sense for the design of products utilizing nanomaterials. In the following sections we will describe three initial attempts to Design for Values tailored to the field of nanotechnology. Firstly, we will describe the 'safety by design' approach of described by Christopher M. Kelty. Next the attempt of Catherine J. Murphy is discussed, who puts forward sustainability as a design criterion for the production and usage of nanoparticles. Finally, we will explain the closely related approach of Johannes F. Jacobs et al. in which green chemistry principles are transferred to nanotechnological design practice.

5.3.1.1. Safety by Design

Kelty (2009) describes a 'safety by design' approach, based on an ethnographic study on work done by the National Science Foundation Center for Biological and Environmental Nanotechnology (CBEN) at Rice University in Houston, Texas and the International Council on Nanotechnology (ICON) on the toxicity of buckminsterfullerenes. The ICON established the idea behind the approach and it was further developed together with the CBEN. The approach is an "*attempt to make 'safety' a fundamental property of new nanomaterials: safety by design*" (Kelty 2009 p81) and it is attributed to the work of Vicki Colvin on the C_{60} buckyball. In essence, the described method is a way to go beyond the toxicity implications after-the-fact of production and to design by identifying engineerable properties of new material with respect to toxicity.

In the 'safety by design' approach, safety must be a property of nanomaterials of equal value to other 'fundamental' physical and chemical properties, like specific gravity, thermal conductivity, magnetic permeability, and solubility in water. Safety is thus defined similarly to fundamental terms by bringing in concepts from biology and environmental sciences. In doing so, the safety can be tuned and controlled just like the physical properties of the material product.

Making safety a property on par with other accepted physical and chemical properties is a radial break away from the traditional conception of safety. For toxicologists, safety is a spectrum of risks resulting in adverse effects for living organisms; the risk spectrum concerns man-made materials in relation to complex ecosystems for environmental scientist, while for process engineers safety is inherent to the type and conditions of the manufacturing process as well as the disposal of waste. It is also a break away from the general idea that one first develops a beneficial application, before testing and verification of potential negative consequences. This idea is most prominent in the notion that it is the responsibility of regularity agencies and corporations to test and judge the safety of nanomaterials before commercialization, not the responsibility of scientists that discover and characterizes these nanomaterials.

For the safety by design approach to work, it requires that toxicity must not solely be placed in a 'language of hazard, exposure and risk', but also in a 'language of engineering and control of matter'. In other words, the toxicity of nanomaterials "*exists, but it is an interesting problem for materials chemists and nanotechnologists—one related to the properties of the material, its derivatizations, and its surface chemistry*" (Kelty 2009). In light of the 'safety by design' approach the research into the toxicity of nanomaterials is one of concern ('is the material toxic?') and control ('how can the toxicity be modified?'). The approach thus implies that while toxicological research is essential for discerning how to engineer towards safety, it is insufficient to only inquire about the risks and hazards of every new material. The approach thus re-opens inquiries about the predictability of toxicological effects; however to date very little data exists to effectively implement the approach directly in engineering design. Nonetheless, we think this approach can be a fruitful starting point for research and development to incorporate the value of safety as a driver.

We think that approach has a lot in common with the 'inherent safety' concept that is mainly used in process industry to make an inherent safer design and would like to refer the reader to the chapter on safety by Neelke Doorn and Sven Ove Hansson (2014). Nevertheless, it should be noted that nanotechnology opens the possibility to change the properties by designing the nanomaterial, while in other fields the focus is mainly on exchanging hazardous substances and processes for less harmful alternatives.

5.3.1.2. Design for Sustainability

Catherine J. Murphy (2008) proposes that sustainability should be used as a design criterion for the synthesis as well as application of nanoparticles. She provides the example of quantum dot synthesis. Quantum dots are nanosized semiconductors that have interesting properties for lasers, light emitting diodes, photodetectors, photo-imaging, solar cells, and transistors, due to confinement effects that result from their limited size. Most quantum dots are made of binary alloys such as cadmium selenide, cadmium sulfide, or cadmium telluride. However, the synthesis methods are far from sustainable. The feedstock used for the regular synthesis route is dimethylcadmium, which has several problems from a sustainability perspective, such as (a) the substance is very toxic, (b) is a known human carcinogen, and (c) poses explosion danger at temperatures used in the synthesis. Murphy shows that using sustainability as a design criterion can result in the discovery of more benign feedstock such as cadmium oxide or cadmium. She also puts forward investigations in manganese doped zinc selenide as an alternative to the cadmium based quatum dots, in an attempt to open up the design space for more sustainable production methods.

Murphy provides a second example with gold nanoparticles that have interesting optical properties that could be utilized in imaging technologies or as a chemical catalyst. Currently, these nanoparticles are produced using benzene and diborane, which are known to be toxic. Furthermore, the downstream processing requires huge amounts of organic solvents. Murphy (2008) shows that research with sustainability in mind generated a production process for these gold nanoparticles that replaced the two toxic substances with more benign alternatives, used less organic solvent for the membrane filtration, and decreased the overall production cost with a factor of about 100. Furthermore, she described ongoing research efforts with the aim to develop more sustainable processes for gold nanoparticle production that use water as the solvent, take place at room temperature, and utilizing mild reducing agents by using surface for the particle growth.

As a general approach for the more sustainable production of metal nanoparticles, Murphy (2008) proposes the use of metal salts in a water solvent with biological reduction agents. These processes are in general more benign substances and mild operation conditions, in effect reducing energy usage and lowering the potential impact on workers as well as the environment. A second approach put forward by Murphy is coating the nanoparticles in such a way that they become more benign. This approach depends on the observation that most biological interaction at the nanoscale is highly dependent on the surface of the nanoparticle instead of the composition of the core. Nonetheless, we find this second approach failing in two respects. First of all, the coating of nanoparticle makes recycling of the particles more difficult, because it is a mixture of substances. Secondly, the coating only provides a layer of protection – that will inevitably fail over times - instead of designing the particle to be inherently less poisonous.

Rightfully, Murphy also points towards the potential of nanomaterials in environmental friendly applications - such an environmental remediation and solar cells - as a way towards the adoption of the sustainability criterion for the utilization of nanotechnology instead of only the production of nanomaterials. Nonetheless, we think that further research is necessary that incorporates the whole life-cycle (including the production and disposal of the utilized nanomaterials) to see if such applications are overall more sustainable.

5.3.1.3. Green Nanoprinciples

Like the design for sustainability approach by Catherine J. Murphy discussed above, some authors have taken inspiration from green chemistry, especially because in the recent years 'green chemistry' has been successfully utilized to reduce or eliminate the usage and generation of hazardous substances in the design, manufacture and application of chemical products. For example Lallie C. McKenzie and James E. Hutchison (2004) see an opportunity for the cross fertilization between the fields of green chemistry and nanoscience. They state that: "*the principles of green chemistry can guide responsible development of nanoscience, while the new strategies of nanoscience can fuel the development of greener products and processes*". The idea has inspired the term 'green nanotechnology' to which topic a journal, named the International Journal of Green Nanotechnology, is dedicated since 2009.

Green chemistry is a set of twelve principles,[8] developed by Paul Anastas and John C. Warner (1998), which can be used to guide engineering design in chemical technology towards safety and sustainability. To transfer the approach from chemical technology to nanotechnology, an abstraction is needed to translate the approach from one discipline to the other. Jacobs et al. (2010) proposes to abstract the twelve principles of green chemistry into four general concepts, knowingly:

- Product safety
- Low environmental impact
- Material & energy efficiency
- Process safety

The concept of 'product safety' entails the aim of designing nanoproducts in such a way that they represent a low potential for generating hazards, while maintaining their desired function. The 'safety by design' approach, as described by Christopher M. Kelty (see section 5.3.1.1), fits nicely with the safety value of this concept. The 'low environmental impact' concept aims for a product design that incorporates a whole life-cycle view. In other words, the concept looks for nanoproducts, which are produced from renewable resources and are reusable, recyclable, or degradable into non-environmentally-persistent components. The third concept indicates a need for the conservation of utilized resources in as far as possible. The concept aims for the value of sustainability by maximizing the incorporation of material into the final product and minimizing the utilization of energy. The 'process safety' principle aims at the value of safety form the perspective of the production process. The nanoproduct manufacturing process should inherently pose as little hazards as possible for the workers and environment as well as have adequate safety features lowering the risk of potential process hazards.

The approach of using existing knowledge and know-how of more established fields of technology in order to aim for the incorporation of moral values such as safety and sustainability into design of nanotechnology seems to be a fruitful way to prevent the reoccurrence of known moral issues with technological development.

5.3.2. Long-Term Approaches

As stated in the introduction, for long-term developments a Design for Values approach is more difficult than for short-term developments, because there is still speculation about what the artifacts-to-be-designed will be like. Nevertheless, the terms 'design' and even 'design considerations' do feature in nanotechnology literature.[9] Ethical considerations are not yet found in such references, though. But the values at stake do seem to be clear (see 5.2.3.2). The real challenge is to deal with the issue of traditional categories (natural-artificial, healthy-ill, human-machine, and the like) for ascribing values becoming problematic (see table 5.2). Martijntje Smits has suggested using a strategy that she called 'taming the monster'. Here the term 'monster' refers to the fear people get when they come across products that cannot be immediately put into a certain traditional category (Smits 2006). This means that we have to redefine our categories such that the new technology can be characterized and understood in terms of the new categories. Although at first sight this seems an attractive option to deal with these problems, one can question if it does justice to the concerns one may have. Does redefining the categories solve the problem or does it walk away from them by means of a conceptual 'trick'? Are these categories purely epistemic and is there really no ontologic aspect to these categories? In other words: is the problem only in our thinking, or is it also in the reality outside our minds?

Table 5.2: Challenged traditional categories of long-term application of nanotechnology.[10]

Type 1	Type 2	Nature of confusion
Human	Machine	Extreme close connection between human and machine ('cyborg')
Natural	Artificial	Engineered processes that mirror exactly the natural processes
Healthy	Ill	State of knowing the chances of certain potential diseases becoming actual
Living	Non-living	Building up tissue from scratch with unclear transition from non-living to living
Mortal	Immortal	Extending the lifespan at will

Another difficulty for ethical reflection on long-term developments in nanotechnology was the difficulty to imagine possible effects. Here, too, a proposal has been done to solve this difficulty, namely that of 'techno-moral' scenario's (Boenink et al. 2010). This tool is meant to enhance imagination in cases where consequences of technology are not obvious. Of course, this tool functions primarily in the context of a consequentionalist approach to ethical problems and if one does not adhere such an approach, the value may be limited. Both the 'monster taming' and the 'techno-moral scenario' approaches have the disadvantage that they only support the long-term development assessments, but they do not provide clues for Design for Values. At best, they help to gain insight into what values are at stake. As long as there values are ones we that we know from past or current ethical debates, the stage of 'monster taming' and/or 'techno-moral scenario' building can be followed by a stage in which existing approaches for Design for Values are applied, as then we are again in a known domain.

5.3.3. Comparison and Evaluation

When we compare short- and long-term developments, we see that in the short-term Design for Values plays a role in the nanotechnological developments, be it a relatively small one. In the long-term developments of nanotechnology, there is no concrete elaboration of the notion of Design for Values yet, but there are efforts to get more view on what values are at stake. Due to blurring of boundaries between traditional categories, it is difficult to relate values to categories as a preliminary step towards Design for Values. The extent to which category boundaries really will get blurred is, however, unclear as it is difficult to picture a realistic image of what the effects of nanotechnological developments might look like. However, scenario techniques, such as the techno-moral scenarios, may help to get more clarity here, and this may lead to taking the next step towards Design for Values, as the relation between values and (new) categories can then be identified.

5.4. Experiences and Examples

As in the previous section, we make a similar distinction in time frame. The short-term will be illustrated with the application on nanoparticles in sunscreens, while cyborgs will be the example of long-term nanotechnological developments.

5.4.1. Nanoparticles for Sunscreens

Nanoparticles of titanium dioxide (TiO_2) are currently utilized in a wide variety of products. These TiO_2 particles are, for example, used as UV protective agents in cosmetic sunscreen and plastics, but also as photocatalysts for the photodegradation of pollutants in wastewater and cancer treatments, or as coating for 'self-cleaning' windows. For this case study, we will focus on the sunscreen application, because sunscreens containing nanosized TiO_2 are sold worldwide for over a decade now and it is one of the most widely known first generation nanotechnological products.

As we are dealing with a cosmetic product, it is clear that the value of safety is at stake. Safety is here mostly related with possible negative effects on human health, but also to the hazards associated with the manufacturing process. When considering the whole life-cycle of the product, it is obvious that sustainability is also a moral value that is at stake with the manufacturing process, required resources and disposal. Jacobs et al. (2010) has shown that by using the 'green nano principles' for the current production methods as well as for the design of the final product some noteworthy advances can be made in designing for the moral values of safety (see section 5.3.1.3). The analysis shows that there is still a large room for improvement left with regard to safety and especially sustainability. For example, Jacobs et al. discusses the widely acknowledged problem with the formation of reactive oxygen species (ROS) when TiO_2 nanoparticles are excited with UV light. These formed ROS are known to cause negative health effects on humans and pose ecological risks. The issue can be reduced by designing the nanoparticle in such a way that it consist of a crystal morphology that is less photo-active and hence produces less ROS. Besides, doping the particles with another metal or coating the TiO_2 surface with silica, alumina and/or polymers can reduce the production of ROS. Most of these ways to reduce the ROS formation are currently employed by production companies for TiO_2 nanoparticles intended for sunscreen applications.

On the other hand, Jacobs et al. (2010) shows that the current manufacturing practice does not follow a design for sustainability approach. One issue is that the raw materials for the production are obtained from non-renewable resources, such as the mining of titanium containing ore for natural deposits. Other sustainability issues are the use of chlorine gas as well as extreme operational conditions posing environmental risks as well as a high consumption of energy in the form of combustion agents, such as ethane or hydrogen. It should be noted that the used high temperatures - in the range of 900°C - also pose hazards to the workers.

Overall, it seems that although there are some examples of application of Design for Values with respect to safety for first generation nanoparticle containing products, only minor efforts for the design for sustainability have been undertaken. Other moral values that are potentially at stake have received even less attention, not in the least because there is currently a clear lack of Design for Values approaches specific to nanotechnology.

5.4.2. Cyborgs

One of the promises of the application of nanotechnologies in the domain of health care is the enhancement of human capabilities through extremely smooth transitions from human beings to artifacts. Human brain cells may be directly connected to computer wires. This will create a hybrid being that most commonly is called a cyborg. Transhumanists hope that this will also enable us to store our mind in hardware so that we can live on forever. Ray Kurzweil in this context uses the term 'singularity', the complete integration of humans and machines (Kurzweil 2005). Ethical questions have been raised about this and some suggestions have been made about Design for Values considerations. Although, the term eugenics is carefully avoided in most writings about human enhancement, no doubt because of its negative connotations, a fear for the development of a sort of super-being is sometimes expressed. In itself the idea of human enhancement through technology is far from new. The philosopher Ernst Kapp already suggested that all technology in some way or other is an extension of the human body.[11] Also the idea of extending the human mind through technology has been suggested, for example in the extended mind theory developed by Andrew and David Chalmers. But in those writings all examples are such that it is well possible to indicate where the human part of the human-machine combination ends and where the machine part begins. This, however, would be much more problematic in the case of cyborgs and the singularity. This causes category boundary definition problems, as discussed in 5.3.2, particularly in the human-machine and mortal-immortal categories.

One of the primary values at stake here is human dignity (Rubin 2008). Some authors have suggested design criteria for human-machine combinations of a cyborg-like nature that aim at preserving this dignity. Jeff Wildgen, for instance, refers to Asimov's 'classic' three laws[12] for robot design as a possible set of criteria that also hold for singularity-related designs (Wildgen 2011). Machiel van der Loos (2007) also refers to Asimov's laws and suggests that cyborgs will be designed to have agency and for that reason ethical constraints should be in the list of requirements, just like Asimov suggested for robots. He mentions the condition of the cyborg having control over the implants as another dignity-related ethical requirement for cyborg design. This also relates to the integrity of the human personality as a moral value at stake here. According to Kevin Warwick - who had a silicon chip transponder implanted in his upper left arm himself - merging human and machine will have an impact on the individual's consciousness and personality (Warwick 2003). The option of linking persons through the transponders, for instance, means that they are no longer individuals but very intimately connected to other people's minds. Warwick suggests that cyborgs may develop their own type of consciousness and their own morality related to that.

5.5. Open Issues and Further Work

Research initiatives on nanotechnology can be found all over the world. Even upcoming economies such as Argentina, Brazil, China, India, Philippines, South Africa, and Thailand are now investing in nanoscience and technology (Salamanca-Beuntello et al. 2005). Nanotechnology is turning global and the cultural diversity of perceptions of ethical issues due to differences in cultural heritage, economic conditions as well as political situations should thus also be addressed (Schummer 2006). Currently, the majority of scholars working on Design for Values specifically for nanotechnology are based in the USA and Europe. Although, the presented approaches are broad enough to embrace some cultural diversity, there is a need for Design for Values approaches from a non-Western perspective.

As nanotechnology is a relatively new technological field its development is still plagued by uncertainties. These uncertainties are the result of lack of knowledge, ignorance, and complexity. Ignorance, also called the 'unknown unknown', is a very troubling part of uncertainty of a novel technology, because we do not know what we have to prepare ourselves for. A Design for Values approach should be able to deal with these kinds of uncertainty that plague the conception and initial implementation of a technology. Vermaas et al. (2011) have suggested the designers should take into account robustness, flexibility and transparency to deal with this issue. We think that adaptability over time, dependent on the new information that comes available, is an appropriate starting point for a Design for Values approach that wants to deal with this uncertainty issue. Alternatively one could choose to wait for further development of the technology before aiming at Design for Values approaches. However, the 'Collingridge Dilemma' (Collingridge 1980) makes clear that the impact of steering the development in light of moral values is the greatest in the initial phases of development, but unfortunately there is a limited amount of knowledge available at that moment.

A complicating issue with nanotechnology is the diversity of materials and techniques that it represents. Nanomaterials themselves can be the product of nanotechnology, or could be used to manufacture products that do not contain nanomaterials. Even when only nanomaterials are considered, the diversity is extremely large as a result of the numerous ways a nanoparticle of a given composition can be made functional for specific applications. A nanoparticle of a given composition can have various morphologies, crystal structures, size distributions, and agglomeration or aggregation states. This heterogeneity asks for a Design for Values approach that can deal with this diversity and can incorporate various analyses, which are made on a case-by-case basis. For example, to evaluate the toxicity risk of a chemical substance it is needed to assess the toxicity hazard as well as the exposure of a nanoparticle. In current chemical risk assessment the exposure is characterized with a measure of concentration; however, such a measure is not always adequate for nanoparticles due to the above-mentioned issues of size distribution, shape, aggregation, etcetera. A design for safety approach thus should be flexible enough to incorporate this diversity.

For the long-term considerations, the issue of seemingly confused category boundaries needs more exploration. As Geertsema has pointed out, whether one accepts the blurring of category boundaries depends on one's ontological assumptions (Geertsema 2006). If this is the case, the problem of confused boundaries may exist only for certain ontological stances and not for others. This will have consequences, of course, for the moral questions related to these boundaries.

5.6. Conclusion

In this chapter we have shown that nanotechnology is a field of new and emerging technology that brings about relatively new ethical issues, in particular for the long-term. For the short-term, no fundamentally novel values are at stake and there are some first initiatives aimed at Design for Values. With respect to the long-term, ascribing values to categories is hampered by the fact that some traditional category boundaries are blurred in the case certain expectations appear to be realizable. In particular molecular nanotechnology may cause truly novel ethical issues due to the blurring of boundaries. Scenario techniques can be used to get a clearer picture of what the technology may look like and this may speed up the development of Design for Values.

Endnotes

[1] Here we take the term Design for Values in a sense that is wider than 'value-sensitive design'; see Van den Hoven J, Manders-Huits N (2009) Value-sensitive design. In: Berg Olsen JK, Perdesen SA, Hendricks VF (ed) A companion to the philosophy of technology. Chichester, Wiley-Blackwell, pp 477-480.

[2] The online inventory can be found at http://www.nanotechproject.org/inventories/

[3] The animation can be viewed at http://www.youtube.com/watch?v=zqyZ9bFl_qg and was sponsored by Nanorex, Inc.

[4] In the science fiction movie Bicentennial Man this is even mentioned as the ultimate distinction between robots and humans. For a reflection on the way science fiction movies deal with the theme of blurring boundaries between humans and machines, see Cornea C (2008) Figurations of the cyborg in contemporary science fiction. In: Seed D (ed) A companion to science fiction. Oxford, Blackwell Publishing, pp 275-288.

[5] This is not a new concern. It was expressed, for instance, already by C.S. Lewis in his book The Abolition of Man. At that time he was referring to the use of eugenics by the Nazi's, but his objections seem strikingly applicable to human enhancement as he explicitly writes about the creation of humans with enhanced capabilities.

[6] Here, again, we see science fiction movies playing with that theme, for instance the movie Gattaca in which a man can only participate in space travel if he delivers a friend's blood, hair, skin cell, and urine samples, because he himself has a defect in his DNA.

[7] Here we use the distinction between prescriptive and proscriptive morality. Proscriptive morality is focused on what we ought not to do and is inhibition-based, while prescriptive is focused on what we ought to do and is activation-based.

[8] These principles are: (1) Waste prevention, (2) Atom economy, (3) Less hazardous synthesis, (4) Design safer materials, (5) Safer auxiliaries and solvents, (6) Design for energy efficiency, (7) Renewable resources, (8) Reduce derivatives, (9) Catalysis, (10) Design for end of useful life, (11) Real-time monitoring, and (12) Inherent safer processes.

[9] For example, Merkle RC (1996) Design considerations for an assembler. Nanotechnology 7: 210-215, and Choi HS, Liu W, Nasr F, Misra K, Bawendi MG, Frangioni JV (2010) Design considerations for tumor-targeted nanoparticles. Nature Nanotechnology 5: 42-47.

[10] This table is based on Boenink et al. (2010).

[11] See the resent analysis by Lawson (2010).

[12] These laws are: (1) A robot may not injure a human being or, through inaction, allow a human being to come to harm, (2) a robot must obey orders given to it by human beings, except where

such orders would conflict with the First Law and (3) a robot must protect its own existence as long as such protection does not conflict with the First or Second Law. Asimov introduced these laws in a 1942 short story called Runaround.

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Chapter 6

The tech is out there, you can't make it go away.

Laurence Dominic – Epitaph One

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Chapter 6: Towards Safety and Sustainability by Design - Nano-sized TiO_2 in Sunscreens

Abstract

The application of safety and sustainability in the design and production of nanomaterials is complicated by the existing focus on the potential impact of nano-products, diversity of the nanotechnological field, and the Collingridge dilemma. We will argue that retrospective learning for established disciplines and studying environmental, health, and safety (EHS) issues on a case-by-case basis can be used as an alternative way of coping with these three problems. The approach will be illustrated in a case study on novel sunscreens that contain nano-sized titanium dioxide (TiO_2) particles by applying four concepts derived from the twelve green chemistry principles.

6.1. Introduction

Nanotechnology is an emerging field that can provide a broad range of new applications in various technologies and industries, such as cosmetics, electronics, foods, and healthcare. The National Science Foundation has estimated that by 2015 this technology will be a trillion dollar market. Thus far, nanoscience and nanotechnology research efforts have been focused on discovering new applications and nanomaterials with novel properties. Many applications of nanotechnology promise benefits to human health and the environment. Nevertheless, the potential environmental, health, and safety (EHS) issues associated with the new properties of nanomaterials are largely unknown and thus may lead to unintended negative consequences. This knowledge gap is largely the result of limited research focused on these EHS issues (Hannah and Thompson 2008).

This lack of information on EHS issues has been one of the foremost reasons for warnings and calls against the use or application of nanotechnological products. Several non-governmental organizations (NGOs) have demanded severe precautionary measures, including temporary bans or even total moratoria on nanomaterials in consumer products. For example, the International Center for Technology Assessment (CTA) together with 13 other NGOs - including Greenpeace, Action Group on Erosion, Technology and Concentration (ETC group), and the Consumers Union - have petitioned the Environmental Protection Agency (EPA) to regulated nano-sized silver particles containing products as "*illegal pesticide products with unapproved health benefit claims*" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (International Center for Technology Assessment 2008). Friends of Earth has also taken a firm stance against nanoparticle containing products. In their report on cosmetic containing nanomaterials they call for: "…*a moratorium on the further commercial release of personal care products that contain engineered nanomaterials, and the withdrawal of such products currently on the market, until adequate, publicly available, peer-reviewed safety studies have been* *completed, and adequate regulations have been put in place to protect the general public, the workers manufacturing these products and the environmental systems in which waste products will be released*." (Friends of the Earth 2006, p. 17). The UK's Soil Association has even banned the use of nanomaterials from their certified products to safeguard the public since "*the risks of nanotechnology are still largely unknown, untested and unpredictable*." (Soil Association 2008, p. 20).

The ethical issues raised by EHS aspects are essential ingredients of a responsible approach to the development of nanotechnology. Responsible development is a necessary prerequisite for public acceptance of the technology. Fortunately, there seems to be a broad agreement among stakeholders and regulators on the need to promote research on potential EHS effects of nanotechnology (Fairbrother and Fairbrother 2009; National Science and Technology Council 2008; Scientific Committee on Emerging and Newly Identified Health Risks 2009). Moreover, the Royal Institute of International Affairs stresses the need for international coordination of such EHS research efforts (Breggin et al. 2009). Hence the nanotechnology field aims to gain widespread acceptance by addressing the EHS issues throughout the research, design, manufacture, and marketing of nanomaterial containing products.

6.2. Addressing EHS Issues

Addressing environmental, health, and safety (EHS) issues throughout research, design, manufacture, and marketing phases is currently complicated by three factors, knowingly (1) the diversity of nanotechnology, (2) current focus of EHS research on nanotechnological products, and (3) the Collingridge dilemma. This is not to say that there are no other difficulties in dealing or managing EHS aspects of nanotechnology, such as the question whether nanotechnology should be regulated differently than other technologies. However, the three factors given above represent the main factors that underlay many of the problems currently faced addressing EHS issues.

6.2.1. Diversity of Nanotechnology

Nanotechnology as a field is very heterogeneous. The diversity of the field becomes already apparent by comparing some products, for example, the buckminsterfullerenes, carbon nanotubes, gold nanoparticles, quantum dots, and ZnO nanowires (Singh and Nalwa 2007). These few groups of nanomaterials already represent a large variety in applications and EHS issues. Functionalization of these various nanoparticles to tailor-make the material for specific applications further increases this diversity. For example, the surface of gold nanoparticles is being modified by various ligands such as fluorescent dyes and antibodies (Shenoy et al. 2006). Depending on the modifications the nanoparticle can be used as a cellular probe, delivery agents, or stimulus for specific biological sites. Each of these different functionalizations give rise to various kinds of EHS issues, for example waste production by its manufacturing process or altered toxicity profile of the modified nanoparticle. The diversity of nanotechnology is further increased by the fact that the field is not confined to products that contain nanomaterials, but extends to technology that can be used to fabricate products that do not contain nanoparticles themselves, by applying nanomaterials in the production process. As a result of this heterogeneous nature of the field, it is nearly impossible to make general claims about EHS issues of nanotechnology. As a result EHS research should utilize a case-by-case approach. This complicates EHS research on nanotechnology, because such research is then faced with an extremely large and increasing number of subject materials and processes to investigate.

6.2.2. Focus on Nano-Products

A second issue with current EHS research on nanotechnology is the persistent focus on products containing nanomaterials. The manufacturing process and exploitation of raw materials get relatively little attention, while all stages in the life-cycle are important for a full assessment of the EHS issues in nanotechnology. For example, some nanomaterial production processes utilize high amounts of energy, apply ecological toxic surfactants, and produce large amounts of waste streams.

This focus on nano-products is also present in policy documents, for example the National Nanotechnology Initiative in the United States has formulated an extensive multi-million dollar EHS research program coordinated by the Nanotechnology Environmental and Health Implications Working Group. This program is "*focused in particular on understanding general mechanisms of biological interaction with nanomaterials and on developing broadly useful tools and tests for characterizing and measuring nanomaterials in various environments*" (National Science and Technology Council 2008, p. 3) and as a result in current EHS research projects the nanomaterial production and raw material utilization are only marginally addressed.

Furthermore, there is a steadily expanding body of literature on nanoparticle toxicity (Crosera et al. 2009; Oberdörster et al. 2005; Singh and Nalwa 2007). This is not to say that all the toxicity issues of nanomaterials are resolved and no further EHS research in this area should be done. However, the lack in EHS on the non-product related issues in nanotechnology begs the question how researchers and engineers should utilize this toxicity information to design more safe and sustainable production processes. A wider view in EHS research is needed to address all EHS issues from raw materials, manufacturing to application and disposal of nanomaterial containing products.

6.2.3. Collingridge Dilemma

Nanotechnology is like other technologies subject to the dilemma of social control (van de Poel 2008). This problem has become known as the Collingridge dilemma. This dilemma refers to the fact that forecasting future effects of new technology has a severe limitation, because at the initial stages of development there is insufficient knowledge to do so; whereas in later phases when issues become clear the possibility to steer the technology is constrained, because the technology has become embedded in society (Collingridge 1980). Collingridge argued to deal with the dilemma by developing technologies that retain the ability to change, in other words that are correctable and flexible for instance by a capability for multiple configurations. Others have advocated developing better forecasting methods that for example do not necessary try to predict future effect, but explore prospective consequences with the use of scenarios (Wiek et al. 2009).

Although forecasting and flexibility are both useful approaches to deal with the dilemma that surrounds the addressing of EHS issues in nanotechnology an alternative approach is retrospective learning from past experience with existing technologies. In the design of previous technologies the Collingridge dilemma made it difficult to implement changes towards solving EHS issues when they became apparent due to their social entrenchment. Nonetheless, the knowledge gained on EHS issues from these older technologies can in principle be used for the design of nanotechnology. However, the gained knowledge on EHS issues is not directly applicable due to the differences between the old and new technology. This knowledge should be translated by abstracting the principles that have become known into more general applicable concepts. These concepts obtained from experience can then be applied in the development of the emerging technology. In such a way, one can at least prevent that similar EHS issues come to bear on the new technology as well. To illustrate this approach we will show, in a case study on titanium dioxide (TiO_2) nanoparticles for sunscreen applications, that principles from green chemistry can be used to address EHS issues in nanotechnology.

The green chemistry approach was selected because it potentially can deal with the 'diversity of nanotechnology' and 'focus on nano-product' factors complicating the handling of current EHS issues in nanotechnology. First of all, green chemistry was developed for the chemical industry, especially to reduce or eliminate the use or generation of hazardous substances in the design, manufacturing, and application of chemical products. As such the green approach is well suited to address EHS issues of nanotechnology in the manufacturing process as well as the nanomaterial containing product. Secondly, green chemistry has been applied to a wide range of chemical products and processes and the approach is therefore expected to be suitable to cope with the high diversity of nanotechnology.

6.3. Titanium Dioxide

To develop the case study we will introduce nano-sized titanium dioxide (TiO_2) that is utilized in UV protector in cosmetic sunscreens and its current manufacturing process. Nano-sized TiO_2 is different from the more well-known micronized form that is used as a pigment for its clear white appearance. Nanoparticles of TiO_2 have electrical and optical properties that are being applied in commercial applications. The photocatalytic properties of nano-sized TiO_2 are used in the photodegradation of pollutants, purification of wastewater, and even cancer treatments. These types of application rely on the ability of TiO_2 nanoparticles to form reactive oxygen species (ROS) when excited with UV light. The photovoltaic properties of nano-sized TiO_2 are being applied in solar cells, while its superhydrophilicity found application in 'self-cleaning' windows and ceramics. Finally, the light scattering and absorption properties of nano-sized TiO_2 can be used for UV protection in applications such as paints, plastics and cosmetic sunscreens.

In adhering to the advocated case-by-case approach in dealing with EHS issues of nanotechnology we will particularly focus on the cosmetic sunscreen application of TiO_2 nanoparticles. The nano-sized particles are applied in sunscreens as an alternative to the so called chemical UV absorbers, such as p-aminobenzoic acid and benzophenones. These chemical UV absorbers are known to lose their protective over time, because the chemicals undergo decomposition when exposed to UV radiation. Furthermore, some chemical UV absorbers can cause allergic reactions in sensitive individuals. Moreover, physical sunscreens, such as nano-sized TiO_2, provide a wider range of UV protection compared to the chemical compounds. It should be noted that sunscreen lotions are generally marketed as cosmetic products in most countries including the European Union, however in the United States sunscreens are treated as over-the-counter (OTC) drugs under oversight of the US Food and Drug Administration (FDA).

The sunscreen application of nano-sized TiO_2 was selected, since sunscreens containing the particle are already on the market for over a decade. Furthermore, the application has become one of the most widely-used examples of first generation nanotechnological products. Moreover, the focusing on a particular nanomaterial and application focuses the case study in such a way that the heterogeneity is limited in such an extent that it becomes manageable. The focus has thus removed the extremely large heterogeneity of the whole nanotechnological field, reducing it to some case-specific diversity. In the TiO_2 nanoparticles case the specific diversity can be found in: (a) particle size and size distribution, (b) agglomeration and aggregation, (c) particle morphology, (d) crystal structure, (e) purity and doping, (f) coating, and (g) the surrounding matrix (Jacobs et al. 2010).

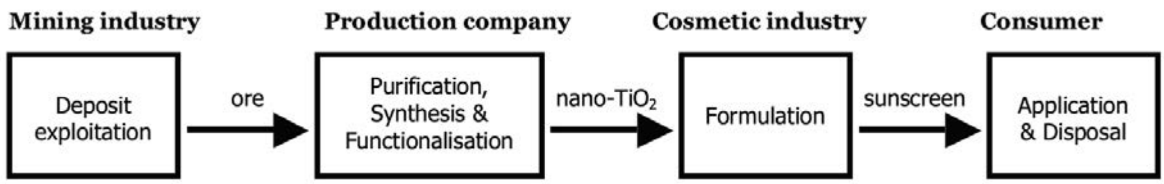

Figure 6.1: Production chain of titanium dioxide (TiO_2) nanoparticles for sunscreens.

Nanoparticles for cosmetic sunscreens do not only give rise to EHS issues as a commercial product. Also the whole production chain (see figure 6.1), including raw material exploitation and manufacturing, should be considered. The production chain of nano-sized TiO_2 production starts with the mining of ilmenit, leucoxene, or natural rutile ore. If the titanium content in the ore is too low it is upgraded via the Benelite or Becher process (Winkler 2003). There are two distinct process routes for the further extraction and purification of the titanium from the processed ore, knowingly the sulfate process and chloride process. For the production of the nano-sized TiO_2 for sunscreen applications the chloride process is generally preferred (Tanaka et al. 2002). In this process the titanium containing ore is reacted with carbon and chlorine gas to form titanium tetrachloride ($TiCl_4$) and separated from contaminants. The purified $TiCl_4$ is then oxidized with oxygen and/or steam in a burner to form TiO_2 particles. (Musick et al. 2007; Meyer et al. 2006). This process was already utilized to produce the pigment grade TiO_2 of micronized size, but the burner nozzle and oxidation conditions were adapted to produce nano-sized particles.

The nano-sized TiO_2 particles are then heat-treated to produce the wanted crystalline structure (anatase or rutile) and after that the crystalline nanoparticles are functionalized by coating for specific client demands. The coated nano-sized TiO_2 is sold to the cosmetic industry who apply the nanoparticles in their UV lotions and creams (see figure 6.1). The sunscreens are consequently sold to the general public through retailers. After use the TiO_2 nanoparticles are being deposed of by washing or rinsing them off the skin they were applied to.

6.4. Green Chemistry

Green chemistry has been employed successfully[1] in the chemical industry to encourage addressing EHS aspects in the design of chemical products and processes by reducing or eliminating the use and generation of hazardous substances. The twelve principles of green chemistry were developed by Paul Anastas and John C. Warner (1998) and a summary of these principles is given in table 6.1.

Table 6.1: Summary of the twelve principles of green chemistry

Principle	Description
1. Waste prevention	Preventing waste production is preferred above treating the waste afterwards.
2. Atom economy	Manufacturing should be designed to maximize the incorporation of raw materials used into the final product.
3. Less hazardous synthesis	Production methods should be designed to use and generate substances that pose minimum of toxicity.
4. Design safer materials	Products should be designed preserve efficacy of function while minimizing their toxicity.
5. Safer auxiliaries and solvents	The use of additional substances should be reduced and innocuous when needed.
6. Design for energy efficiency	Energy requirements of processes should be minimized.
7. Renewable resources	Raw materials or feedstock should be renewable rather than depleting.
8. Reduce derivatives	Unnecessary chemical derivatization steps should be minimized.
9. Catalysis	Catalytic reagents are superior to stoichiometric reagents.
10. Design for end of useful life	Chemical products should be designed for reuse, recycle, or beneficial disposal.
11. Real-time monitoring	Methodologies to allow in-process monitoring and control for optimum manufacturing.
12. Inherent safer processes	Substances used in the manufacturing should be chosen to minimize potential for accidents.

The twelve principles of green chemistry show that this green chemistry approach does not solely addresses EHS issues of the final product; the approach also incorporates EHS aspects of the manufacturing process itself. This approach is therefore considered appropriate for use in nanotechnology to overcome the current focus on nano-products. Furthermore, the green chemistry approach has been successfully applied in the preparation of highly functionalized products, for example pharmaceuticals. These diverse chemical substances have a strong correlation with the heterogeneous nature of nanomaterial containing products. Overall, the green chemistry method seems to be well suited to address EHS aspects in nanotechnology.

6.5. Green Nano-TiO_2

Green chemistry was developed for chemical technology, so before one can apply the green approach to nanotechnology abstraction is necessary. The abstraction of the approach should be conducted in such a way that the method can be translated from one discipline to another. Abstracting the twelve green principles of green chemistry resulted into several concepts with overlapping functionality. The redundancy in the concepts could be removed by combining them into four generally applicable concepts, which are presented in table 6.2.

Table 6.2: Four concepts for green nanotechnology.

General concept	Used green chemistry principles
Product safety	4
Low environmental impact	7 and 10
Material & energy efficiency	1, 2, 6, 8, 9, and 11
Process safety	3, 5, 11, and 12

The four concepts, knowingly product safety, low environmental impact, material & energy efficiency, and process safety, have been implemented in our case study on nano-sized TiO_2 in cosmetic sunscreens to address EHS issues. Below the values are further described and possible applications for TiO_2 nanoparticles are given.

6.5.1. Product Safety

With the 'product safety' one aims at designing products in such a way that they have an as low as possible potential for generating hazards such as toxicity, while still maintaining their desired function. With regard to the case study this means that the nano-TiO_2 particle should still maintain its clear appearance and high UV attenuation, while minimizing any potential toxic effect.

It is known that TiO_2 nanoparticles can form reactive oxygen species (ROS) on its surface when excited with UV light and these ROS can cause toxic effects on humans as well as in the environment. From a product safety perspective this unwanted photo-activity should be removed or suppressed. A possible way to lower the photo-activity of nano-TiO_2 particles is to select a specific crystal morphology of TiO_2 that produces the least amount of ROS. The rutile crystal structure is less photo-active than the anatase crystal structure and thus the former should be preferred. Furthermore, TiO_2 nanoparticles can be surface coated with for example silica, alumina and/or various polymers to prevent contact of the TiO_2 with its surrounding, reducing its photo-activity considerably (Siddiquey et al. 2007; Serpone et al. 2006). Because inorganic coatings can complicate the recycling of titanium dioxide after its useful life and of use non-renewable resources organic coatings are preferred (see low environmental impact concept). Another way to reduce the unwanted photo-activity TiO_2 nanoparticles is by intentionally contaminating the crystal structure by doping with other metals (Anpo 2004). This doping is for example implemented by the company Oxonica-Croda, which use manganese to reduce the photo-activity of their nano-sized TiO_2 UV attenuator marketed under the name Optisol. However, doping has a potential drawback, because the added metal can complicate recycling or generate alternative ways of toxicity.

Another EHS issues with nano-sized TiO_2 is that there is still no consensus about the penetration of these small particles through the skin. Although, more and more publications claim that normal skin forms a sufficient barrier, other studies suggest that a compromised skin, such as diseased, sunburned, or affected by allergies, could provide an insufficient barrier (Mortensen et al. 2008). Although, there is no consensus on this penetration issue the utilization of TiO_2 nanoparticles could be made safer by incorporation into a larger structure. In this way the TiO_2 remains to provide a clear and effective UV filter, but the possibility of penetration is reduced. The Sunjin Chemical Corporation has already produced such UV attenuators by fixating the nano-sized TiO_2 particle in silica beads.

6.5.2. Low Environmental Impact

The 'low environmental impact' value implies that one should look for solutions in the product design so that products at the end of their functional life are reused, recycled, or broken down into innocuous degradation products and do not persist in the environment. Furthermore, raw materials or feedstock used for the production should be as much as possible of a renewable source.

Currently there is no end-of-life strategy for TiO_2 nanoparticles that have been utilized in cosmetic sunscreens. After application they are rinsed off by washing or bathing. Waste treatment facilities are unequipped for the removal of nanoparticles from wastewater (Reijnders 2006), so currently there is no recovery of the particle possible. A possible solution could be to encapsulate the TiO_2 nanoparticle in a larger structure to enhance its recoverability. An alternative route is to create larger particles after the nanoparticles have performed their function, by utilizing the natural tendency of nanomaterials to form larger structures by agglomeration and aggregation.

Raw materials used in the production of nano-sized TiO_2 are presently mostly obtained from non-renewable sources. For example, titanium ore is obtained by mining natural deposits. This stresses the need for recovery of the TiO_2 nanomaterial after its useful life so the titanium can be recycled and depletion of natural resources can be diminished. Other raw materials utilized in the manufacturing process could potentially be gained from renewable resources. For example, to purify the titanium in the chloride process large amounts of carbon is needed, which is obtainable from plant sources. Although the chlorine gas that is needed in the manufacturing process is not from renewable feedstock, its burden on the environment can be decreased dramatically by efficient recycling within the process.

6.5.3. Material and Energy Efficiency

The concept of 'material & energy efficiency' indicates the need for conserving any utilized resources. For the manufacturing process this implies that one strives for maximizing the incorporation or recycling of materials, because it is better to prevent waste than to treat or clean up waste after it has been created. Furthermore, energy requirements of the process should be minimized to lower environmental and economic impacts.

Titanium dioxide nanoparticles are now normally made by flame synthesis after purification by the chloride process. Although the material efficiency of the flame synthesis based on titanium usage is high, it utilizes combustion fuels such as hydrogen or ethane to reach the needed high temperatures in the range of 900°C. Several researchers have tried to reduce or even eliminate the use of these fuels by laser or microwave assisted synthesis methods. An alternative way to reduce material waste and so increase efficiency is to find a suitable application for waste streams. For example, iron salts that are produced during the purification steps of the process could be sold as water treatment chemical. Also the sodium hypochlorite (NaClO) from the off-gas cleaners could be sold as a bleaching agent.

Currently, the flame synthesis is operated at high temperatures and the required heat treatment for crystallization also uses temperatures in the range of 1,000°C. To reduce energy needs it is therefore preferred to manufacture at benign temperatures and pressures. Alternative synthesis routes such as micro-emulsions operate at about 150°C and do not require heat treatment (Andersson et al. 2002). However, in these kinds of processes environmentally unfriendly surfactants and organic solvents are frequently applied. Recently, Li and co-workers have shown that β-cyclodextrin can be used as a benign biodegradable alternative to the use of surfactants in TiO_2 nanomaterial synthesis (Li et al. 2006). Furthermore, super critical fluids can be used as an environmentally friendly alternative to organic solvents. Jawwad Darr and coworkers have shown that supercritical carbon dioxide is a viable alternative in the production of nano-sized TiO_2 (Darr et al. 2005).

6.5.4. Process Safety

The manufacturing process should be as safe as possible, both for the sake of employees as well as to prevent possible environmental hazards. Process safety can be achieved by selecting production methods that are inherently safe, so are designed to minimize the potential for chemical accidents and apply materials that possess either little or no toxicity to human health and the environment. During manufacturing in-process monitoring and real-time control are essential for hazardous reduction and processes should be equipped accordingly.

The International Agency for Research on Cancer (IARC) has classified TiO_2 as possibly carcinogenic to humans (International Agency for Research on Cancer 2006). The currently used chloride process is a gas-phase process, in which the TiO_2 is produced as a very fine dust. To prevent inhalation by workers ventilation and contamination measures are taken. However, by changing to a liquid phase process such as the sol-gel or emulsion method inherently less nanoparticle dust is being created. A drawback of these types of liquid phase processes is that they use solvents that make separation procedures more problematic.

Recently, there have also been attempts to create an alternative production process that uses micro-organisms in the synthesis of TiO_2 nanoparticles (Jha et al. 2009). In this way the manufacturing is inherently safer due to the application of benign process conditions and is also more environmentally friendly, since almost all the raw materials are renewable.

6.6. Conclusions

It is very important to address environmental, health, and safety (EHS) issues for a responsible development of nanotechnology and its acceptance in society. Addressing EHS issues throughout research, design, manufacture, and marketing phases is not straightforward, because it is complicated by the diversity of nanotechnology, the existing focus in EHS research on nano-product, and the information and control problem of the Collingridge dilemma.

We have argued that learning from past efforts to address EHS of existing technologies is an additional route to cope with the Collingridge dilemma. The retrospective learning method can work in conjunction with other ways to deal with the Collingridge dilemma such as improved forecasting techniques and technological flexibility. In order to learn from former technologies the differences between disciplines has to be bridged, which can be achieved by abstraction of the adopted EHS approach into more generally applicable concepts or values. These concepts can then be applied in the novel technology to prevent the reoccurrence of specific EHS issues in the development of the emerging technology. By repeating this over time, an iterative learning process is created that improves our understanding of these concepts and EHS issues and supports the responsible development of novel technologies.

The learning approach was applied, by abstraction of the twelve principles of green chemistry into four green concepts (product safety, low environmental impact, material & energy efficiency and, process safety), in a case study on TiO_2 nanoparticles for cosmetic sunscreen applications. The TiO_2 sunscreen case showed that the approach could broaden the EHS assessment from the focus on nano-product to the whole production chain of manufacturing nanoparticles. Retrospective learning from the green chemistry approach also provided a wider view on EHS issues and the approach was able to handle the heterogeneity of the nanotechnological field. All in all it proved possible to learn from past experience of EHS studies on existing technologies and apply the abstracted concepts to append general methods of addressing EHS aspects of emerging technologies.

Endnotes

[1] Some very successful applications of the twelve principles of green chemistry in chemical design, manufacture, and use, have been granted the Presidential Green Chemistry Challenge Award by the US Environmental Protection Agency (http://www.epa.gov/gcc/pubs/pgcc/past.html).

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Chapter 7

Our brains have always outraced our hearts.
Our science charges ahead, our souls lag behind.

Lee Adama – Daybreak

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Chapter 7: Sunscreens with Titanium Dioxide (TiO_2) Nano-particles - A Societal Experiment

Abstract

The risks of novel technologies, such as nano(bio)technology cannot be fully assessed due to the existing uncertainties surrounding their introduction into society. Consequently, the introduction of innovative technologies can be conceptualised as a societal experiment, which is a helpful approach to evaluate moral acceptability. This approach is illustrated with the marketing of sunscreens containing nano-sized titanium dioxide (TiO_2) particles. We argue that the marketing of this TiO_2 nanomaterial in UV protective cosmetics is ethically undesirable, since it violates four reasonable moral conditions for societal experimentation (absence of alternatives, controllability, limited informed consent, and continuing evaluation). To remedy the current way nano-sized TiO_2 containing sunscreens are utilised, we suggest five complementing actions (closing the gap, setup monitoring tools, continuing review, designing for safety, and regulative improvements) so that its marketing can become more acceptable.

7.1. Introduction

The current debate about the impact of nanoparticles on environmental, health, and safety (EHS) issues is frustrated by the high level of discord surrounding nanotechnology (Berube 2008). Part of the confusion started with the rhetoric used to promote nanotechnology and heralding the novel technology as the next industrial revolution. After warnings from environmentalists and civil activists groups (CAGs) the tone changed and nanotechnology was portrayed not as a revolution, but more as a gradual evolution of science and engineering. Nonetheless, the novelty of nanotechnology was claimed to emerge from the unique properties of known materials at the nano-scale. This claim led to concerns that the risk profile of such material could also be unique and so additional as well as new safety measures ought to be taken. In turn, this even lead some CAGs to demand severe precautionary measures including a total moratorium on nanotechnology (Arnall 2003; Friends of the Earth 2009). In the middle of this debate the confusion was increased by agencies that are responsible to advice on the toxicity level of used substances. For example, the International Agency of Research on Cancer (IARC) classified titanium dioxide (TiO_2) as a possible human carcinogen – in group 2B - (International Agency of Research on Cancer 2006), while the hazards of nano-sized TiO_2 in sunscreen applications were fiercely debated. However, the IARC recognised that TiO_2 particles are being used in various sizes (nano and fine-sized particles), though the agency does not make this size distinction for the given classification. The agency increased the discord further by basing the classification on the results of animal experiments and indicating in its conclusions that human epidemiological cohort studies to support this classification suffer from methodological limitations.

The discord in the current nanotechnology debate is not solely the result of communication issues such as rhetoric, mix-ups, hype, over-claiming and misunderstandings. The debate is also highly technical, heterogeneous and plagued by uncertainty. The diversity of the field becomes apparent by comparing, for example, the buckminsterfullerene C_{60}, carbon nanotubes, silver nanoparticles and quantum dots (Singh et al. 2007). These examples represent just a few groups of nanomaterials and already they have very varied uses and risk profiles. This diversity is further increased by the many different ways in which these various nanomaterials can be functionalised for specific applications. For example, doping or coating these nanomaterials will give them other functional properties and also different risk profiles. The diversity of the nanotechnological field is even larger than only products that contain nanomaterials. The technology can also be applied to use nanomaterials to fabricate products that do not contain nanoparticles themselves. As a result of this diverse nature of nanotechnology, it is nearly impossible to make general claims about EHS issues of nanotechnology, nor is it possible to make such claims on nanoparticle groups (such as nano-sized TiO_2 particles) due to their heterogeneity. Therefore, different nanomaterials and their applications should be analysed on a case-by-case basis.

Besides the diversity of the nanotechnological field and its applications, the debate on EHS aspects is also greatly affected by the uncertainties that surround nanotechnology. As a result of these uncertainties, it is at the moment, generally acknowledged that we do not know enough about nanomaterials to claim that they are safe. At the same time, due to the same uncertainties, the opposite claim of certain dangerousness can also not be made credibly. The general public is highly apprehensive about these uncertainties and EHS researchers are giving guarded answers due to the same uncertainties, it seems clear that most parties in the debate ask for more research into EHS issues (Fairbrother et al. 2009; Scientific Committee on Emerging and Newly Identified Health Risks 2009; U.S.Environmental Protection Agency 2009). However, it is still unclear how much data is needed to give a final and credible answer to these issues. Dealing with the uncertainties of the possible implication of novel technologies, such as nanotechnology, seems necessary for a more meaningful deliberation about their introduction into society.

7.2. Titanium Dioxide

The ethical aspects of the EHS issues surrounding nanoparticles in light of uncertainty will be illustrated by a case study on nanoparticles made primarily of titanium dioxide (TiO_2) used as a UV protector in cosmetic sunscreens. Nano-sized TiO_2 is different from the well-known micronized form that is used for its clear white appearance as a pigment in coatings, paints, cosmetics, paper, and food stuffs. This large-sized form of TiO_2 is known as titanium white or pigment white 6 for pigment applications, while it is often referred to as E171 in food applications. In contrast TiO_2 nanoparticles have various interesting electrical and optical properties that can be utilized in commercial applications. The photocatalytic properties of nano-sized TiO_2 are used in the photodegradation of pollutants, treatment of wastewater, and destruction of tumour cells. These applications mostly rely on the ability of TiO_2 nanoparticles to form reactive oxygen species (ROS) on its surface when excited with UV light. There are also investigations into the use of its catalytic properties for the production of hydrogen. Nano-sized TiO_2 also has photovoltaic properties which can be used in cells for producing electricity from light, while its superhydrophilicity can be applied in 'self-cleaning' windows and ceramics. The electrochromatic qualities of TiO_2 nanoparticles can potentially be applied in windows that colour when a small voltage is applied, while its ability to absorb substances has been investigated for hydrogen storage and sensing applications. Finally, the light scattering and absorption properties of nano-sized TiO_2 can be used for UV protection in applications such as paints, plastics, and cosmetic sunscreens.

For the case study in this chapter, we focus on the cosmetic sunscreen utilisation of TiO_2 nanoparticles. The nano-sized particles are used in sunscreens as an alternative to existing chemical UV absorbers, such as p-aminobenzoic acid and benzophenones, which can cause allergic reactions in sensitive individuals. Sunscreen lotions are generally marketed as cosmetic products in most countries including the European Union. In the United States however, sunscreens are treated as over-the-counter (OTC) drugs under oversight of the US Food and Drug Administration (FDA).

This specific utilisation of nano-sized TiO_2 was selected since it has already been marketed for over a decade and has become one of the most widely-used examples of present (first generation) nanotechnological applications. Focusing upon such a specific case study may seem to narrow the case so that it loses the heterogeneity that is so prevailing in the nanotechnological field. However, the case still harbours the very specific diversity related to the nanotechnological field and the case-by-case approach is in line with the advocated way of approaching nanotechnological issues. The heterogeneity of TiO_2 nanoparticles for sunscreen applications can be found in the following factors:

- Particle size measures and distribution.
- Agglomeration and aggregation.
- Morphology of the particle.
- Crystal structure.
- Purity and doping.
- Use of coatings.
- Surrounding matrix.

The size measure of particles is generally used to define materials as nano-sized. This kind of definition based on a measured size seems straightforward; nonetheless it is subject to several difficulties. The first complication is the comparison of the size measure due to the different ways the particle size can be measured and calculated. Size measurements are based on a collection of nanoparticles and so the calculated average size of the collection can be represented on volume, weight, or area basis. Furthermore, the measurement devices generally use specific environments, such as hydrodynamic or aerodynamic, and require pre-treatment methods for measuring, which can lead to misrepresenting the actual size in applied circumstances. A second complicating factor is that the particle collections have a specific distribution of sizes. This distribution of particle sizes is the result of the production processes and is specific for the applied conditions (Zhao et al. 2005). So representing the collection by only an average particle-size measure does not indicate how varied that size distribution of the collection is. Thus the size measure alone does not give all the information about the used nanoparticle that is needed to differentiate between collections with potential different properties and risk profiles. For example, a collection with an average particle size of 150 nm is considered not a nanomaterial under most accepted definitions that set the size limit at 100 nm. However, this collection can contain a certain fraction of particles that are smaller than 100 nm and thus contains nanoparticles. It is therefore difficult to compare used nanoparticles based on size measures alone. A third complication is caused by the fact that nanoparticles, such as TiO_2 nanomaterials, tend to agglomerate and aggregate into larger structures (French et al. 2009). This assemblage into larger structures alters the actual properties of the material and can thus change the risk profile as well as the effectiveness of the application. The agglomeration and aggregation effects are also environmentally dependent and so sample preparation before size measurements is very critical to insure that the sample is a valid representation of the actual effective particle size in application conditions.

Titanium dioxide nanoparticles can also be produced in various morphologies, such as spheres, tubes, rods, and wires (Chen et al. 2007). Furthermore, titanium dioxide can exist in various crystal morphologies of which anatase and rutile are the most prominent. These different crystal structures also give various properties to nano-TiO_2. For example, the rutile has a lower density, higher refractive index, and is less photo-active than the anatase crystal structure. Another factor of the heterogeneity of TiO_2 nanoparticles for sunscreen applications can be found in the purity of the particle. Due to production methods or intentionally contaminating the crystal structure (doping) with other metals the properties of the nano-TiO_2 can be changed (Anpo 2004). This doping is for example implemented by the company Oxonica-Croda, which uses manganese to reduce the unwanted photo-activity of the nano-sized TiO_2 marketed under the name Optisol.

To utilise TiO_2 nanoparticles in sunscreens, they are normally surface coated with silica, alumina and/or various polymers to (a) increase its stability in the lotion or cream and (b) reduce its photo-activity (Siddiquey et al. 2007; Serpone et al. 2006). Not only the material used for the surface coatings, but also its thickness, its chemical purity, and the use of multiple coatings, increase the heterogeneity of the utilised TiO_2 nanoparticles further. The use of coatings also raises questions about its effectiveness to reduce the unwanted photo-activity, durability of the coating layer in the whole life-cycle, and the recyclability of these particles. Another factor in the diversity of nano-sized TiO_2 is not the particle itself, but the matrix in which the particle resides. The nanoparticles can, for example, be fixated in a matrix, such as silica beads with nano-sized TiO_2 particle of Sunjin Chemical Corporation, or glued together by the used surface coating. Together these factors lead to a large diversity in nano-sized TiO_2 particles used in cosmetic sunscreens. As will be shown below, this heterogeneity results in more uncertainties, which forms a barrier to assess and manage the risks of nanomaterials.

7.3. Risk Assessment and Management

To assess the risk of technological applications, the hazards should first be identified and the exposure predicted. Then the negative effect and exposure need to be correlated in such a way that the resulting risk can be characterised and classified. The relation between the impact of the undesirable event and the probability of its occurrence is generally defined as the product between the two. In this way the hazard phenomenon is specified quantitatively into risk. It is thus clear that the assessment and management of technological risk requires knowledge of the possible effects of application, the exposure, and the relationship between the effects and the exposure. This knowledge is generally based on statistical data and toxicological studies; however such information is mostly unavailable for novel technologies due to the uncertainties that surround them during conception and initial implementation.

These uncertainties are caused by a number of underlying factors, of which (a) lack of knowledge, (b) ignorance, and (c) complexity are the most prominent. In a situation where we know the effects, but cannot attribute probabilities to the likelihood of its occurrence we speak of lack of knowledge or 'known unknowns'. This knowledge gap can generally be overcome by gathering more information. However, during the conception and initial implementation of a technology, not all likelihoods can be quantified. With nano-sized TiO_2, for example, there is still no consensus about the penetration of these nanoparticles through the skin. Initial studies indicated that nano-TiO_2 particles could penetrate the skin, however these results were refuted, since the methodology could not differentiate between penetrated particles and particles trapped in hair follicles (Nohynek et al. 2007). Currently, studies suggest that compromised skin - such as diseased, sunburned, or physically damaged dermis - could provide an insufficient barrier (Mortensen et al. 2008). Another example of such uncertainties is the conflicting results in literature, because of the different measures for exposure doses - based on mass, area, or particle number – that are utilised and in practice hard to convert into each other (Oberdorster 2000; Wittmaack 2007; Sager et al. 2009). A final illustration of this lack of knowledge is that, besides the two major routes of exposure, specifically inhalation and skin contact, also alternative exposure routes, such as penetration of TiO_2 nanoparticles dust into the brain via nasal exposure (Wang et al. 2008), were and still are only marginally investigated. It is clear that in the case of TiO_2 nanoparticles for sunscreens there are still knowledge gaps in certain areas.

In some cases we even do not know that there is a specific kind of hazard. Targeted gathering of information does not remedy the situation, because we are dealing with what can be called 'unknown unknowns'. Generally this cause of uncertainty is referred to as ignorance and it clouds risk assessment and management, because it is tremendously difficult - if not impossible - to anticipate the consequences of hazards that are unknown to us. Simply put, we do not know what we have to prepare ourselves for. In retrospect, we can illustrate that such a situation has already occurred with nano-sized TiO_2 in a cosmetic sunscreen application. A few years after the introduction of these sunscreens the BlueScope Steel Company investigated the appearance of defects on prepainted steel roofs. They concluded that the defects were the result of extreme weathering, caused by TiO_2 from sunscreen lotions used by workers during installation (Barker et al. 2008).

Thirdly, uncertainty can also be caused by the complexity of causal relations. The causal relation between the agent and the specific effect can be very hard to express due to diffuse system interactions, long term cumulative effects, system adaptability, incoherent dynamics, and subject heterogeneity. The large diversity in utilised TiO_2 nanoparticles, as described above, creates such complexity and so forms a barrier for effective risk assessment and management. This problem can be illustrated by the fact that there are some issues surrounding the interpretation and relevance of toxicological studies. Many toxicological studies of nano-sized TiO_2 use P25 of Evonik Degussa as their object of research. However, the usability of these studies for TiO_2 nanoparticles for sunscreens is at least questionable, because P25 is sold as a catalyst and not for cosmetic application. Moreover P25 is not coated to reduce photo-activity and it is of the anatase crystal type, whereas almost all of the TiO_2 nanoparticles utilised in sunscreens are coated and of the less photo-active rutile type. Another issue is that most toxicological studies on TiO_2 are short term and only look for acute toxicity. For instance Griffitt et al. (2009) studied the effects of nano-sized TiO_2 on Zebrafish in 48-hour experiments. They concluded that it is almost non-toxic in the timeframe studied, however, they also found some alterations in the expression of genes that might lead to negative effect upon long-term exposure. A further hurdle in setting up needed causal relation is that the studies are done under laboratory conditions and on test animals, such as rats, mice and hamsters, which makes it questionable if these represent the actual circumstances in the product's life cycle and if the results can be directly translated to other species. For example, it is already established that the various test rodents have species differentiated responses to TiO_2 nanoparticles (Bermudez et al. 2004).

Finally, ambiguity can contribute to the uncertainties in the EHS debate. Ambiguity refers here to the type of uncertainty in the interpretation or assessment that can be given to EHS data (Renn et al. 2006). For example, one can interpret the conclusion of a study reporting that a certain nanoparticle can cause observable harm above a certain level as a negative effect and claims that avoidance of the material would be wise. In contrast, one could also regard this nanomaterial as safe, because the level is above that of a reference material, which is already used in practice. Although, these ambiguity issues raise ethical questions, the other three factors of uncertainty (lack of knowledge, ignorance, and complexity) also raise ethical issues, which we discuss in further detail below.

7.4. Societal Experimentation

From the current debate about the impact of nanoparticles on (EHS) issues debate it is clear that stakeholders want to have a complete assessment of the possible risks, before the novel technology, such a nanotechnology are being introduced into the market. However, the uncertainties surrounding the novel technology make it essentially impossible to make an early complete risk assessment, because not all information can be available prior to introduction. In principle, only after its introduction the hazards of the technology can be fully assessed. In such case, the introduction would amount to a large-scale societal experiment, to test the hazards of the novel technology (Krohn et al. 1994).

The moral acceptability of such a societal experiment has been investigated by van de Poel (2009, p124). He describes four *prima facie* moral conditions that are helpful to judge the acceptability of a societal experiment in the light of uncertain risks. These seemingly reasonable conditions are: (1) the absence of alternatives, (2) the controllability of the experiment, (3) informed consent, and (4) the proportionality of hazard and benefits. To these acceptability conditions van de Poel adds four responsible set-up requirements: monitoring, feedback, scale, and containment. We will use those requirements as part of the controllability condition, since that is their main aim.[1] In the case of nano-sized TiO_2 in cosmetic sunscreen we will show that the introduction and current practice do not adhere to these four conditions for the moral acceptability of societal experimentation under uncertainty.

7.4.1. Absence of Alternatives

The first acceptability condition is "*to require that first all other methods for gaining knowledge about the actual functioning of a new nanotechnology and its ethical consequences and hazards have been tried out before a societal experiment is carried out*" (van de Poel 2009, p135). This seems a reasonable condition, because large-scale societal experiments generally will pose a greater danger to society than small-scale laboratory tests. So the latter type of experiment is thus generally preferred to societal experiments.

We have examined over 150 laboratory scale toxicological studies that have been published about nano-sized TiO_2. Most of these studies have investigated dermal penetration, inhalation, photo-activity, and cellular damaging. Although still some questions remain on these topics, other topics have hardly received any attention. For example, only a few studies have investigated acute ecological effects or toxicity after oral ingestion. Clearly other acute routes of toxicological risks could have been investigated at laboratory scale before marketing and introducing it into society. In this case there are clearly other methods of testing besides societal experimenting and there seems to be no good reason not to employ these alternatives first. The introduction of nano-sized TiO_2 is thus at odds with the first acceptability condition. Another example is the continued discussion on dose metrics (mass, area, or particle number based) that is appropriate for risk assessment and management of nanoparticles. It seems possible to investigate this at laboratory scale, thus there seems to be no good reason to test this in a large-scale societal experiment.

7.4.2. Controllability of the Experiment

The second moral condition that is proposed in van de Poel (2009) is the controllability of the experiment. The main function of this consequentialist criterion is to prevent potential negative effects to turn into major or irreversible ramifications. To this end, a morally acceptable societal experiment (a) should be monitored, (b) ought to encompass a feedback mechanism, (c) should set up to constrain potential hazards, and (d) ought to be consciously scaled up. Monitoring is essential to control an experiment, because it is the initial step in a feedback mechanism in response to any harm resulting from the experiment. In addition: "*Responsible societal experiments also require that measures are taken to contain the hazards of the experiment*." (van de Poel 2009, p140). This can be achieved with measures such as safety factors and safety barriers to address known risks, but also guard against possible unknown hazards. In view of the fact that experiments are more controllable and it is easier to learn from experiments at smaller scales, is desirable to gradually scale up the societal experiment.

In the TiO_2 case there is essentially neither monitoring nor containment required by law. In Europe and the United States post marketing surveillance is virtually absent. For instance, there is no adverse effect reporting system (Breggin et al. 2009). Although, after-sales monitoring is not legally mandatory, it is questionable whether we are currently technically able to do so. Contemporary methods of detection are poor at distinguishing natural from engineered nano-sized particles. The methods are also unable to cope with the complex nature of environmental samples (Sadik et al. 2009). Another controllability issue is that in practice the TiO_2 nanoparticles are not contained after use. The nanoparticles are readily washed off during swimming or bathing and wastewater treatment facilities are poorly suited for nanoparticle removal, so the TiO_2 nanoparticles can get directly into the environment (Reijnders 2006).

7.4.3. Informed Consent

In light of the fact that societal experiments involve humans, van de Poel (2009) suggests the deontological restriction of informed consent. This restriction entails that an experiment using human subjects is only morally acceptable if the subject has voluntarily agreed to take part and the decision is based on a sufficient knowledge of the expected benefits and potential risks involved. Van de Poel (2009) recognises that there are various issues with the specific application of informed consent to societal experiments, particularly the restrictiveness of the conditions and problems with acquiring the consent from indirectly involved subjects; nonetheless it can be argued that the underlying concern of respect for moral autonomy should be addressed in judging the moral acceptability of a societal experiment.

A major issue with the informed consent condition is that it seems an impossible task to ask all those possibly affected by a novel technology to consent to its application, especially those who are indirectly involved. So, the informed consent criterion should be formulated in such a way that it becomes workable. From a practical standpoint it seems reasonable to request that at least those who are directly affected should be informed. This practical criterion then would also need to encompass the obligation to re-evaluate who is being affected directly. So that during the experiment, when new information comes to light that point towards new group(s) of directly affected, those should immediately be informed. Another issue with the informed consent condition for societal experiments is that it remains questionable, if it is desirable that when one individual raises an objection to a certain hazard, the whole experiment should be abandoned. This is especially problematic, since novel technologies could bring large benefits to more than one individual. The principle seems to be overly restrictive in essentially giving every individual veto power. This predicament could be addressed in a practical sense by giving directly affected individuals a reasonable option to stop the experiment for themselves only. A *reasonable way* means that stopping the experiment would not put an overly large burden on that individual. In practice such a way out could be accomplished by having or keeping alternatives that achieve roughly the same function.

In the TiO_2 case, this limited notion of informing consent would result in only informing primary users of sunscreen lotions containing nano-size TiO_2 by labelling the products as such. Furthermore, the primary users should be able to stop using the sunscreen and switch to an alternative that does not contain these TiO_2 nanoparticles. In the current situation, there is no legal requirement to label sunscreens[2] in such a way that the users are being informed that they contain nano-sized TiO_2 (Breggin et al. 2009). Few commercially available sunscreens are labelled appropriately, mainly because producers expect negative consumer reaction to such labelling. As a consequence of the lack of labelling, consumers are not informed about their involvement in the societal experiment and are unable to terminate their participation in the experiment. Although, it seems at first glance that the consumers of the experimental sunscreen can straightforwardly stop using the product containing the nanoparticles, they are unable to switch to an alternative because it is unknown to them which alternative does not contain the experimental material.

7.4.4. Proportionality of Hazard and Benefits

As a final criterion for judging the moral acceptability of societal experiments van de Poel (2009) proposes to weigh the proportionality of risks and benefits. As described above, uncertainty makes such an assessment impossible, because it is not possible to quantify risks and benefits. As a solution, van de Poel (2009) suggests to weigh expected benefits of the experiment against the credible hazards from the experiment. Therefore, this criterion seems to be a way to rule out extreme experiments, which provide almost no benefit or present very large hazards. However, there is a practical problem with this approach, at least in the case of TiO_2 nanoparticles. The move away from quantitative benefits and risks towards expected benefits and credible risks makes the analysis more speculative. Furthermore, in light of uncertainty resulting from ignorance, the analysis is plagued by being incomplete and the issue will often stay unresolved. A debate about the moral acceptability of the societal experiment based on this criterion will thus most likely run aground, because there is no clear distinction to show credibility of the anticipated hazards or benefits, as already shown in the description of the debates about nanomaterials. In practice, this weighting approach puts the judgement on a slippery slop, which most likely will result in a social stalemate. A possible solution is to consider the most restricted form of such a weighing; only considering quantitative risks and benefits.[3] A societal experiment should then at least provide more quantitative benefits than quantitative risks before it can be considered acceptable.

Another related problem with this criterion is that it seems to suggest that we somehow can make a well-considered decision before the introduction of a novel technology. This is a step away from what the concept of societal experiments stand for, which is to recognise that under uncertainty the implementation of technology should be monitored and continuously evaluated, since uncertainty blinds us to certain effects. So, a stronger argument could be made for continuous evaluation based on the risks and benefits that can be quantified at that time. The 'absence of alternatives' condition already requires gaining as much quantitative knowledge of risks without doing the societal experiment and the proposed criterion then sets an *a priori* burden on the proposer of the societal experiment to quantifiably show that based on current best knowledge the benefits outweigh the risks. Furthermore, during the experiment new information about the risks and benefits will emerge and the continuation of the experiment should than be re-evaluated. In the TiO_2 case there is, however, no clear post-market regulation in either Europe or the United States (Breggin et al. 2009), so its introduction could be considered morally unacceptable according to this criterion as well.

From the above it is clear that the introduction and the continued marketing of cosmetic sunscreens containing TiO_2 nanoparticles can be perceived of as a morally unacceptable societal experiment, since it does not meet any of the reasonable conditions for such experiments. This is mainly the result of not considering the introduction as a societal experiment and this is still hampering better informed risk assessment and management following its introduction. Essentially, the introduction of nano-TiO_2 in sunscreens was and still is a large-scale societal experiment in which no data is being gathered and no learning takes place.

7.5. Towards Acceptability

We will show in this section that the four modified acceptability conditions of societal experimenting could be used to support and guide the introduction of innovative technologies. In general this requires that novel technologies can be monitored and are flexible; so that the technology can be adapted after introduction when new information becomes available via continued monitoring and evaluation. Furthermore, the conditions can also be used to point the way for already applied technologies that could be considered morally unacceptable, such as the TiO_2 nanoparticles in cosmetic sunscreens. In the TiO_2 case one could conceive of five complementing routes to do so, knowingly: (1) closing the existing knowledge gap, (2) monitoring the societal experiment, (3) systematic evaluation of quantifiable risk and benefits, (4) designing for safety, and (5) incorporation the experimental nature of technological introduction into regulation. These five routes based upon the four modified conditions will be discussed below.

7.5.1. Closing Knowledge Gaps

For the nano-sized TiO_2 in sunscreens case, we have shown that there are uncertainties because we lack knowledge on specific hazards. These knowledge gaps could have, and according to the conditions should have, been resolved before introduction of nano-sized TiO_2 in sunscreens. A first step to moral acceptability is thus to close these knowledge gaps, such as the appropriateness of dose metric for toxicity, aggregation/agglomeration state of nano-sized TiO_2 in natural environments, acute oral toxicity, and short-term eco-toxicity. To facilitate these investigations, funds could be made available to support research in these specific directions; alternatively obligations could be set on producers to provide this information before products are allowed onto the market.

7.5.2. Monitoring the Experiment

As the introduction of TiO_2 nanoparticles into sunscreens can be considered a societal experiment, it is clear that the experimental data from this experiment should be measured and recorded. For example, the exposure to these nanoparticles should be investigated for workers, direct users, and those otherwise indirectly affected. Data on production and market volumes are also required to get a good view on possible exposure amounts and long-term ecological fate of the nanoparticles. Other examples of studies are the (bio)accumulation of the TiO_2 nanoparticles, long-term stability of particles and/or applied coatings, mobility in the environment, and chronic toxicity. Furthermore, all the results of these studies should then be combined to give insight into the complex causal relations that play a role in the possible risks associated with the use of nano-sized TiO_2 in sunscreens. It is, however, questionable if these measurements can be done directly, because currently most methodologies are ill-suited for complex samples that need to be investigated. A necessary primary step is thus to put further efforts into the development of analysis tools that can identify specific engineered nanoparticles in complex samples directly.

7.5.3. Continuous Review

The new data that is gained from the societal experiment by monitoring should be used to complement existing information. In turn, this data should be used to support ongoing evaluation and acted upon if necessary. In the nano-sized TiO_2 case, participants should firstly be properly informed in such a way that they at least know that their partaking in a societal experiment. Labelling sunscreen containing nano-sized TiO_2 would be a straightforward way of accomplishing this notification. Nonetheless, currently the industry has scarcely done so without obligation, most likely due to the expected negative reactions after its initial hype, similar to what occurred with genetic modification. A legal obligation to put forward this product information could possibly ensure directly-affected consumers have a way to know and provide these consumers with a possibility to terminate their use. Furthermore, reviewing procedures and strategies for terminating or altering the experiment should be put in place.

7.5.4. Designing for Safety

A further way to moral acceptability could be achieved by engineering design for safety in the sense of societal experimenting. In this kind of design, the experimental nature of technological introduction is taken into account during the design process. One can think of flexible production methods that can be changed when new risk information becomes available to produce a safer or completely other product. In the case of nano-sized TiO_2, this flexibility could be in the form of production units that are not narrowly dedicated, but can be modified rapidly in such a way that it can produce different particle sizes, other crystal types, incorporate different types of coatings, or even utilise a whole different metal oxide. Furthermore, one could think of alternative applications of the same particle when newly discovered traits seem to have negative effects upon the current application. In the TiO_2 case this has already been done with regard to ROS formation. The photoactivity of not coated anatase type TiO_2 nanoparticles are used in remediation of wastewater by utilising the same catalytic effect that made it less suitable for the sunscreen application. So, in a sense these flexible ways of using the novel nanoparticle apply the inherent diversity and changeability of the developing nanotechnological field. A further conceivable option could be designing the product such that it is easier to measure to facilitate the monitoring of the societal experiment, for example by adding tracers. Yet, another way to improve controllability of nanoparticles could be found in making them easy to remove after use. One could think of making the nanomaterial biodegradable or putting the nano-sized particles in a larger matrix so that the whole (nanoparticle embedded in the matrix) become removable by normal waste treatment facilities.

7.5.5. Regulation of Societal Experiments

As the introduction of novel technologies can be conceptualised as a societal experiment, it seems reasonable to create a framework that upholds and supports the moral acceptability of such experiments. Such a framework should not only prevent unacceptable societal experiments *a priori* by striving for sufficient pre-market studies and a proper experimental setup, but in addition should support actual experimenting and continued parallel evaluation during its execution after introduction. In the case of TiO_2 nanoparticles in sunscreens one could think of aiming at studies to close the knowledge gaps; for example toxicity test in areas that have received little attention or with nano-sized TiO_2 particles that are actually used in sunscreens. Furthermore, regulations could be beneficial in supporting post-market surveillance of the product, which is currently only meagrely picked up by the market; this is evident by the almost total lack of product labelling, limited voluntary registration in nanoproduct databases, and the unavailability of market volume data on nanomaterial containing products. Finally, regulation could also be useful in the area of setting up bodies that are able to facilitate (re)evaluation of the information gathered by monitoring the experiment and suggesting adaptations to the execution of the societal experiment.

7.6. Conclusion

The discord in the debate on the EHS aspects of nanotechnology is largely affected by the uncertainties surrounding the technology. Dealing with these uncertainties and their causes is necessary for a more meaningful deliberation about the introduction of technologies into society. We have argued that this introduction of novel technologies, such as the use of TiO_2 nanoparticles in cosmetic sunscreens, can be conceptualised as a societal experiment due to various causes of uncertainties. The moral acceptability of such an experiment can be investigated on the basis of four *prima facie* moral conditions that have been developed by van de Poel (2009). In light of the practical considerations we have proposed to modify the acceptability conditions of societal experimenting into the following:

1. The absence of alternative ways of extending the knowledge required for a complete risk assessment and management.
2. The controllability of the experiment, including monitoring, feedback, scale and containment.
3. Informing directly affected and providing the ability to terminate their personal involvement.
4. The *a priori* and continuous (re)evaluation of risk and benefits based on current and evolving knowledge.

The current practise in the nano-sized TiO_2 sunscreen case seems to violate all four acceptability conditions and so we argued that it constituted a morally unacceptable societal experiment. To remedy this situation we have agued for the following complementing actions:

a. Closing the existing information gap.
b. Setup of monitoring tools and gathering data from the conducted societal experiment.
c. Start continuous evaluation of available quantitative risk and benefits.
d. Ongoing engineering design for safety.
e. Altering legislation so that it incorporates the experimental nature of introducing novel technologies into society.

In a more general sense, it is very helpful to recognising that the introduction of a novel technology into society amounts to a societal experiment and that the moral acceptability of such an innovative technology can be evaluated from this viewpoint.

Endnotes

[1] The set-up requirements have other functions besides controllability. Especially, the monitoring and feedback requirements have an additional function to ensure that data is gathered and ensure learning from the societal experiment.

[2] This situation can change in the EU if the Commission adopts the proposed new regulation for the EU's Cosmetic Directive in which it would be mandatory to file nanomaterials in concentrations of more than one weight percent in the list of ingredients followed by the word 'nano' in brackets.
[3] One could also consider other less restrictive forms of credibility criteria than scientific quantifiability, however, this should be accepted by all stakeholders to prevent the same social stalemate. Scientific quantifiability gives a prevalent way to measure credibility and provides a baseline case that at least should be obtained.

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Chapter 8

CH: Why would take-a-chance cause a rebellion?

PW: Isn't that what any new idea really is about?

Cooper Hawkes & Paul Wang – The Dark Side of the Sun.

Chapter 8: Discussion and Outlook

This thesis has set out to contribute to the acceptable handling of social and ethical issues in engineering design by trying to find the answer to the question: how can design engineers adequately deal with the challenges raised by social and ethical issues under the uncertainties that are typical of innovative design practice? The uncertainties are of research interest, because these are not limited to statistical probabilities. Uncertainties in innovative design also involve limited knowledge (known unknowns), not knowing all possible consequences (unknown unknowns), complexity of numerous casual relationships, and various reasonable interpretations of new data and innovative design concepts (ambiguities). The focus in this thesis has been on two specific challenges in innovative engineering design under uncertainty, knowingly: (1) the selection of the 'best' design concept from among a set of alternatives taking into account social and moral issues and (2) the development of a socially and morally acceptable 'robust' design alternative.

The following three sections will interpret the findings in light of the related research questions. Culminating in an elucidation of the main results for further research by proposing six propositions. The final sections of this thesis will be dedicated to discussing the findings in relation to the broader issues in the study of engineering design, constructing coherent decision tools, responsibilities of engineers, and engineering education.

8.1. Selecting the 'Best' Design

The first part of this thesis (chapters 2, 3, and 4) focuses on the evaluation of design concepts in order to select the 'best' design from among a set of alternatives for further development, while taking into account social and moral considerations. In such selections, several design alternatives are evaluated on several design criteria that include value-laden criteria, such as safety and sustainability. The challenge is to make the societally and ethically laden selection of the 'best' alternative under the uncertainty of innovative engineering design.

In engineering practice, matrix-based selection tools are often used in the decision process and therefore it was analysed whether these tools are methodologically adequate (see chapter 2). The analysis showed that these matrix-based selection tools cannot deal with the lack of available information that is typical for the early stages of innovative design work. The matrix-based selection tools are therefore not well suited for handling unknowns, as the measures are not able to adequately predict the behaviour of the designed artefact nor to envision its application as well as the effect it will bring about. In addition, the presented impossibility theorem shows that the matrix tools can produce inconsistent or paradoxical outcomes, when used to select the 'best' alternative. This negative result applies if the tool aggregates performance or if the tool aggregates preferences measures. The limited amount of information available restricts the measurability of the data so much, that it is not possible to come to an acceptable calculative outcome in all cases. Finally, the selection tools do not resolve issues with making judgments on the various social and ethical relevant trade-offs. This is the result of the incomparability of value-laden performances and preferences. All in all, these severe methodological difficulties indicate that these tools are not well suited for making selections in innovative engineering design, because they can produce incoherent results, cannot handle typical uncertainties, and cannot evaluate value-laden trade-offs.

Nonetheless, the matrix based selection tools are used in design practice and such design processes have delivered society with successful artefacts according to the people involved. Therefore, the use of the decision method for socially and ethically laden selection of design alternatives in innovative design was studied empirically (see chapter 3) to investigate how these methods are used despite of the methodological difficulties as presented in chapter 2. Our investigation shows that in design practice, the matrix-based selection tool is not used to make the actual selection. The matrix is thus not used to prescribe which of the alternatives needs to be selected by the design team. The observations also indicate that the tool is not used to describe how the selection was made. The matrix is thus not used as a written record of the way the 'best' design alternative was chosen.

Given the actual use of the matrix-based tools, the designers are not directly hindered by the methodological difficulties, as formulated in chapter 2, because these difficulties assume that the tool is used to make the selection. Design engineers use the matrix in a rather different fashion. Engineers use the tool to support the selection process in a variety of ways, but the selection is based on their judgment rather than that the tool is used to directly select the 'best' alternative. It was observed that the matrix method supports the decision making process in three distinct ways. The tool enhances creativity, facilitates communication, and provides insights for judgement formation needed for making the socially and ethically laden selection. The provided insight and enhanced creativity can help the design team find alternative design concepts, that avoid the social issues and circumvent recognised ethically laden trade-offs. In other words, the designers are supported in creating a new design concept that solves the identified issue or trade-offs. For example, the designers of a bioethanol production facility modified the design to such an extent that it uses a feedstock that does not compete with food production, making it socially more acceptable. The matrix method also supports the communication between the people involved in the design project, besides providing insight and facilitating creativity. The visual nature of the matrix allows for a presentation of the design decision that can be understood by all stakeholders. The matrix thus allows every stakeholder to participate with knowledge and experience into the formation of the final judgment. The matrix-based tool is thus useful for the design team to deal with social and ethical issues in the decision process, without making the selection for them.

The matrix-based selection tools use performance measures to denote the performance of the design concepts on ethically laden design criteria (e.g., safety or sustainability). This raises the question how such a performance can be measured when supporting the decision making process. In chapter 4, the Fire and Explosion Index (F&EI) is used as an example of a method that is frequently used in design practice to analyse the safety performance of a design alternative. However, the F&EI method is lacking as a performance measurement tool, because the resulting F&EI number was formed using invalid mathematical operations, leading to meaningless results. Furthermore, the F&EI does not provide a representative measure of safety performance, because it cannot be a basis of comparison given the limited amount of information available in innovative design practice. Observations on engineering design projects indicate that the design engineers did not use the F&EI to support the selection process, as it did not seem directly compatible with the matrix-based tool. The designers assess the safety performance based on experience, available data, and comparison between alternatives.

In the current matrix-based selection tools it is unclear how the performance measure of socially and ethically laden design criteria need to be identified, because most tools are silent about the operationalisation of these measures. Therefore, there is a need for methods that provide such performance measures that can be used in engineering design practice. These methods should provide a simple measure of performance that allows for direct comparison in matrix based tools and is compatible with the limited information available in the early design stage. Already accepted indexes, such as the F&EI, can provide a good bases on which to build.

From the three chapters, it is clear that design engineers make the socially and ethically laden selection utilising a pragmatic approach that uses matrix-based tools to form design judgement in open communication with experts and stakeholders. Design judgment is taken here as the formation of a view, after evaluation and deliberation, about the expected functioning of the designed artefact that includes social and ethical aspects. The matrix-based tools are useful to form design judgment as they do provide insight, stimulate the needed creativity, and facilitate communication. Methods that can provide simple performance measures for these matrix-based tools are needed, in order to support the judgment formation that is otherwise mainly based on experience, estimations, and heuristics. Such basis of design judgement formation in innovative design leaves the resulting selection of the 'best' design alterative weak to 'black swan events' (Taleb 2001), if the design concepts are not developed to be robust to the uncertainty that is typical of innovative design.

8.2. Developing a 'Robust' Design

The second part of this thesis (chapters 4, 5, and 6) focuses on the development of a design alternative that is robust with respect to the uncertainties that surround innovative design work. The development of 'robust' design concepts is of major importance, due to the Collingridge dilemma (Collingridge 1980). In the initial phases of technological development, such as the conceptual design phase of innovative technology, changes are easily made; however, the impact is difficult to assess due to the large uncertainties. In the later phases of the development, when the artefact is being produced and used on a large scale, there is more information about the design's impact; however, the technology is entrenched in society and difficult to change. The challenge is to address socially and ethically laden issues in the development of innovate design alternatives in such a way that, on the one hand, the design can cope with the typical uncertainties, and, on the other hand, the artefact can be changed in response to newfound information about the impact. A design concept is considered 'robust', if it is able to adequately deal with this challenge.

The challenge to develop such a 'robust' design was studied in the field of nanotechnology, since this upcoming field spurs many technical innovations under large uncertainties. To set the stage of the analyses, it was firstly enquired what the social and ethical issue are in the development of nanotechnology (see chapter 5). To analyse the social and ethical values at stake, it is necessary to make a distinction between long-term and short-term developments of nanotechnology. In the long-term, the development of nanotechnology may blur traditional category boundaries that are used in ascribing moral values (e.g., human dignity, integrity of human nature, and intergenerational justice). In the short-term, various moral values are at stake, such as equality, justice, privacy, responsibility, safety, and sustainability. These moral values at stake are, as such, not new or unique to nanotechnology, but dependent on the technology that is enabled by the nanotechnology. Nonetheless, short-term developments of nanotechnology give rise to new social and ethical issues by the novel way values are combined, values are brought into conflict, and issues are placed into context (see chapter 5).

In the literature, little attention has been paid to incorporating social and ethical deliberation in the design of nanotechnological artefacts. Some initial attempts for such approaches have been developed for nanotechnology, such as design for safety (Kelty 2009), design for sustainability (Murphy 2008), and scenario techniques (Boenink et al. 2010). However, there are no established methods that are frequently applied in design practice. Therefore, this thesis focuses on forming approaches for the development of 'robust' designs in two different ways. The first way is to adapt existing approaches for addressing social and ethical issues to deal with uncertainty that is typical of innovative design (see chapter 6). Existing approaches can be adapted by abstracting the concepts of the approach, so that they become broad enough to encompass the innovative field and its typical uncertainties. The next step is to tailor the concepts to the specific application. In chapter 6, an example is given by adapting the twelve green principles of green chemistry to an approach for green nanotechnology for the application of nano-sized titanium dioxide particles for cosmetic sunscreen.

Another way to confront the challenge to develop a 'robust' design is to evaluate the moral acceptability of alternatives under uncertainty. The difficulty is that only after its introduction and dissemination into society it is possible to fully assess the consequences the designed artefact has brought about. In the social experimentation approach of Van de Poel (2009) the development of a design alternative is conceptualised as a societal experiment and acceptability can be an assessed on a basis of four conditions (absence of alternatives, controllability, informed involvement, continuous re-evaluation). In chapter 7, the general approach is interpreted for the engineering field of study, as well as a specific application. The approach is shown to be able to evaluate an innovative product design in nanotechnology, knowingly titanium dioxide nano-particles for cosmetic sunscreen applications. The results of the approach are used to recommend actions to improve the design with respect to acceptability. It is thus possible to develop and implement approaches that can support the development of 'robust' design alternatives that consider social and ethical issues under the typical uncertainties of innovative engineering design.

From the three chapters, it is clear that there is a need for approaches to support design engineers in developing design alternatives that are able to cope with the social and ethical issues and are 'robust' to the uncertainties that are typical of innovative design. The goal is to create a 'robust' design that is easy to change or refit in light of new information, usable for different purposes, minimally impacted by assumptions made during the design process, and able to perform well under various circumstances. This thesis shows that approaches to develop such 'robust' designs can be developed by building on existing approaches by abstraction or conceptualisation of those approaches. The approach needs to be tailored to the specific field of applications in which different time horizons needs to be considered as well.

8.3. Dealing with Social and Ethical Issues

Taking together the results of the various studies presented in this thesis, it becomes possible to answer the main question. How can design engineers adequately deal with the challenges raised by social and ethical issues under uncertainty that is typical of innovative design? Design engineers can deal with the challenges raised, by forming design judgement with the help of selection tools, and development approaches in order to design a robust artefact that is:

- adaptable in its configuration,
- flexible in its functioning,
- resilient to design assumptions, and
- resistant to changing circumstances.

This aim for robust design will, in most cases, cost additional design effort and initial economic investment. These additional costs can be justified, because the incorporation of social and ethical issues enhances the social acceptability of the artefact. Furthermore, the cost can also be justified by pointing at the reduction in possible costs, when things turn out differently than expected.

8.4. Propositions

The propositions are a necessary part of a doctoral thesis, though have lost importance over time. Before the twentieth century a thesis would consist only of propositions, while thereafter the thesis would consist of written argumentations, empirical examinations, and/or rational proofs to support the proposed propositions. Currently, the propositions should reflect the researcher's ability to formulate scientifically inspiring questions, not limited to the specific topic of the thesis. These propositions are not physically part of the thesis, but are placed on a separate slip of paper. Following this current tradition, you can find ten propositions accompanying this thesis for your inspiration.

In line with the older tradition and custom of the Laboratory of Physical Chemistry at which I did my MSc graduation work, I have attempted to provide a provocative formulation of the main results of my PhD research into the form of the following six propositions.

1. Information availability in innovative design is the main limitation for calculative decision-making methods.
2. Design engineers use decision tools to support their value-laden judgement formation in such a practical way that they circumvent the methodological issues of the tools.
3. Indexes are a good starting point to build methods that generate performance measures that allow for the early consideration of value-laden design criteria.
4. Approaches for robust and innovative engineering design work require plasticity towards specific applications and time scales of effects.
5. Existing approaches to address social and ethical issues can be adapted to new areas of engineering design by abstraction and successive tailoring for specific applications.
6. The moral acceptability of innovative engineering design can be evaluated by conceptualising the application of the artefact under design as a social experiment.

8.5. Studying Engineering Design

The aim of this thesis is to provide insight in the way design engineers do and should deal with uncertain socially and ethically laden issues in innovative design practice. As this specific subject has received very limited attention in literature, exploratory research was done to gathering initial information to gain familiarity with and insight into the phenomenon, without making explicit hypotheses beforehand. The knowledge gathered provides a basis for more focused and quantitative investigations. The six propositions, as described above, propose some interesting avenues for such research.

The study has focused on the conceptual design stage of innovative engineering design. The conclusions from this study are, therefore, not directly applicable to other parts of the engineering design process. The work presented here can be supplemented by further research into the effects of uncertainty in earlier design stages, such as the feasibility assessment and preliminary design. Exploratory research in these design stages can give a more complete overview of the way engineers deal with uncertainty in relation to socially and ethically laden issues. More advanced design stages and redesign have a very different level of uncertainty in which existing techniques for optimising and statistical uncertainty are valuable tools. Incorporating social and ethical issues in these tools requires very different considerations. This study has focused on innovative design work in the engineering field of (bio)chemistry and nanotechnology. It also would be of interest whether the findings of this study could be confirmed in other fields of engineering. This could be done by studying the early phases of design projects in various fields, such as civil engineering, electrical engineering, and mechanical engineering. It seems reasonable to expect that other specific kinds of approaches and tools are being used for the same general purposes.

There is a need for approaches and tools to support design engineers in selecting design alternatives and creating robust designs. The presented study suggests that these methods must be able to handle the typical uncertainties of innovative design in the early design stages as well as the erratic increase of available information during the design process and artefacts lifetime. Special attention needs to be paid to (a) the lack of information that limits measurability and comparability as well as (b) the limitation of forecasting that blurs consideration of the possible effects the artefact can bring about. Building on existing approaches and tools, which are already used in design practice and subsequent tailoring to specific applications, seems a promising way forward.

8.6. Coherent Design Decisions

Making decisions is an integral part of engineering design work and many tools have been developed to support design engineers (Okudan and Tauhid 2008). In chapter 2, it has been argued that matrix based selection tools can produce inconsistent or paradoxical outcomes by presenting impossibly theorems for aggregation of performance and preferences measures. The scope of the investigation was limited to selection tools that use a matrix structure; however, the theorems are formulated in such a general manner that the results can be extended to other selection methods that want to achieve coherence. The theorems place great demands on the required inputs and severely limits the construction of coherent methods for design selection.

Lennon et al. (2013) have compared five selection methods in the conceptual design of a new microplasma device. They show that the methods indicate different design concepts as the desired alternative. This issue of different outputs is related to the way these methods try to get away from the impossibility theorem. The methods each relax the conditions set in the theorem differently, resulting in incoherent outputs. For example, the weighted sum method of Pahl and Beitz does not adhere to the independence of irrelevant concepts condition (see chapter 2) and the ELECTRE method utilises intransitive relations (Roy 1991) thus relaxing the unrestricted scope condition. All in all, relaxing the conditions of the theorem lead to methods that provide an incoherent selection of the ‘best’ design.

Another way out of the impossibility theorems is demanding richer input data in the form of comparability of performance measures. The additional information gained by comparability allows for possible aggregation methods. However, this seems an infeasible strategy in engineering design, especially if value-laden criteria are considered (see chapter 2). Comparability of preferences also seems a very ambitious requirement in practice.

Yet another approach in building a coherent tool to support design making is asking a different question. In the current setup, the theorem shows an impossibility result, if one is looking for an ordering over all alternatives. One could image that the designers would also be helped, if a method could just indicate a single winner or a group of 'good' design alternatives. In other words, the method would look for a desired product or process design family from among a set of alternative design concepts. However, a very similar move has already been investigated in social choice theory. A coherent preference aggregation of this type also runs into an impossibility result, if the output is one or several winning alternatives. This negative result is described in the Muller-Satterthwaite theorem, which has a very similar setup to Arrow's theorem (Reny 2001). In light of the striking similarities between preference and performance aggregation (see chapter 2), it seems unlikely that this approach would lead to positive results in the field of engineering.

A possible way around this issue is to stop looking for a winner, but to start identifying the losers. This type of approach would inform the design engineer about the design alternatives that should not be selected. In other words, the tool would aim to coherently limit the alternatives to a small set on which a judgment needs to be made. For example, the method can eliminate all alternatives that are Pareto dominated on all criteria by at least one other alternative. This kind for Patero-dominance method would reduce the set of alternative to non-dominated alternatives. It should be noted that a dominance relation is difficult to satisfy in the sense that it will only eliminate a few alternatives. In practice, the larger the array of criteria that is considered, the smaller the amount of dominance relations, hence fewer alternatives will be dropped. This approach could thus provide tools that are coherent, but would only be of limited applicability in engineering design practice.

In social choice theory many of the ways to circumvent the impossibility theorems have been investigated for preference aggregation and these could be extended to performance aggregation with some minor modifications. The development of new design methods for engineering design should thus take notice of the results of social choice theory in order to prevent reinventing the wheel.

8.7. Taking Responsibility

In discussing the responsibility of engineers for their designed artefacts and the effects they may bring about, I want to get two general misconceptions out of the way. Firstly, the notion that design engineers are not responsible for the effects that the artefact brings about, because the artefact is value neutral. The National Rifle Association of America (NRA) with their statement expresses this very clearly by stating that: "*guns don't kill people, people kill people*". It is correct that the artefacts cannot be hold moral culpable, only people can (Koepsel 2010). However, this does not relieve the engineer from his moral duty. A weapon is intentionally designed to inflict harm, while other more benign artefacts are not. Secondly, the misconception that ethics is the realm of managers/politicians and therefore engineering design needs only to keep within the limits defined by laws, regulations, and codes. This is yet another way of passing the buck. Design engineers are in a better position to reveal and control the artefact. Furthermore, it seems unrealistic to assume that current laws, regulations, and codes can deal with all innovative designs and every possible effect the artefacts can bring about. This is supported by the many changes made in the aftermath of technological disasters in order to prevent their occurrence in the future.

In order for design judgement to lead to an acceptable design alternative, it should not only be based on the know-how and experiences of a single design engineer, but it should be based on the information available from all stakeholders. Many people would then contribute to the formation of judgement. Therefore, it will be difficult to assign responsibility, because it is very difficult to find out who contributed to what extend to the resulting undesirable event. This issue is known as 'the problem of many hands' (Thompson 1980). A possible way out is to allocate responsibility to the involved individual with the most expertise on the topic or the one that hold the most power in the process. This is in line with the present legal atmosphere in which professionals are personally held accountable for mistakes that brought about harm (Dekker 2012). Engineering has not been fully affected by this trend, since technical design flaws are, mostly, indirectly generating fatal consequences and many actors are involved in the design process. Nonetheless, it is reasonable to expect that victims of the negative effects of technical design flaw want amends and will drag the failing engineer in front of the court. Employers of these engineers are in a difficult position. The company is being put in a bad light by the accusation towards their employee and it seems very attractive to put the blame on a single person instead of on the whole organisation. For this to work, it is required that there is a clear division of labour with an allocation of responsibilities connected to the work done. This is very hard to accomplish given the complexity, heterogeneity, and inherent uncertainties of the design process. Nonetheless, many companies have responded to legal responsibility by putting into place more and more procedures. An increasing amount of professional associations and committees add to this development by setting up procedures in handbooks, guidelines, and codes of conduct. In these kind of procedures it is written down who should do what, how it should be done, and in what way the steps in the process needs to be reported. In principle, this allows one to trace down the individual mistake that led to the accident.

With this trend in mind, it seems that the tools and approaches discussed in this thesis could not only support the design engineer in making better design judgement and creating more robust designs. These tools and approaches could also lead to a more procedural way of engineering design and thus add to the blaming of individual engineers. This criminalisation of human shortcomings is problematic, because we should realise that faults are bound to happen in the practice of a profession. First of all, it is human to make mistakes, especially, when faced with the very limited information. Secondly, engineering profession can learn from mistakes. The field is full of successful designs that are built on the back of previous failures (Petroski 2006). Furthermore, a mistake can only become an accident within a failing socio-technological system. Hence, collective responsibility needs to be assigned for the failing of the system. The responsibility is thus a complex interplay of personal responsibilities by various stakeholders and a collective responsibility for the system in which the artefact is utilised, designed, and redesigned.

Design engineers thus need to cultivate the personal moral responsibility. These engineers owe a duty to those they are working for and to those who fall victim to the resulting technological disaster. The engineer needs to assess their motivation and intent by introspection as well as weigh the probable benefits with the gravity of possible harms. From the perspective of the socio-technological system the challenge is to organise the design process in such a way that it "*further*[s] *individual ethical behaviour, stimulates ethical deliberation, reflection and decision-making, minimises the occurrence of undesirable effects, and stimulates the occurrence of desirable effects*" (Van de Poel 2001, p442). The controls by the system should not suffocate individual responsibility, but leave room to owe up to ones duty by a shared responsibility (Coeckelbergh 2006). Institutions and regulatory bodies should encourage this way of working, create the conditions to enhance ethical consideration, and provide the opportunity to learn from near misses and mistakes. In a similar vein, the tools in this thesis can be applied to support designers to address social and ethical issues in the initial stages of the design process.

8.8. Educating Design Engineers

In the first part of this thesis observations were made of design projects done at the Delft University of Technology. These capstone design courses have become a regular component in nearly every discipline of engineering education. The development of these design courses is primary stimulated by industry and educators, who express the need for graduates that are better prepared for engineering practice on the job (Dutson et al. 1997; Dym et al. 2005). The capstone design projects got secured in the engineering curriculum by requirements of the accreditation agencies, such as the Accreditation Board for Engineering and Technology (ABET), the Institution of Chemical Engineers (IChemE), and the European Network for Accreditation of Engineering Education (ENAEE). The capstone courses have developed over time from mostly artificial projects devised by design educators into realistic projects that are provided and supported by industrial partners.

Capstone design projects are generally provided in the later phase of the engineering curriculum after mathematics, natural science, and engineering science subjects have been taught. The placement of these capstone design projects in the end of the programme is based on the idea that students need a critical mass in understanding 'fundamental' subjects, before they can meaningfully engage in design activities. This curriculum structure is thus grounded in the belief that engineering is an instrumental process requiring the application of rational scientific theory and methods (Bucciarelli 2003). This notion is strengthened by the way accreditation agencies envisage a suitable engineering program. The IChemE calls basic training in mathematical and scientific understanding the 'underpinning' of chemical engineering education (IChemE 2009). Along the same lines, the ABET envisions training in mathematics and basic sciences as the 'roots' for engineering sciences, which itself should form the 'bridge' between mathematics and other basic sciences on the one hand, and design practice on the other hand (ABET 2010). In essence, engineering design is viewed as an instrumental process requiring the application of rational scientific theory. This notion entails an applied science view on design.

Several authors are very critical of the current emphasis placed on mathematical as well as scientific methods to solve practical engineering problems, and some authors have even suggested that the applied science view has had a negative effect on the student's performance in engineering design projects (Downey and Lucena 2003; Otto and Wood 1999; Sheppard 2001; Thompson 2009). In a curriculum based on the applied science view, engineering students are mainly taught a highly reductive analytical way of engaging with problems that are presented as having only one unique solution (Bucciarelli 2003). This is most recognisable in the problems addressed in engineering science, natural science, and mathematics courses, which have precisely specified 'givens', admit to a single solution via one specific method, avoid any ambiguity or uncertainty, and little to no attention is given to the context or situation in which the problem might actually be encountered in practice. The analytical methodology of dealing with engineering issues that is advocated in this manner is in sharp contrast with the widely recognised fact that the contextual and underdetermined nature of design tasks require a broader spectrum of skills and approaches in which analysis plays an essential role, but in which judgement and reflection are at least equally important (Auzenne et al. 2006; Dym 2006).

The tools in this thesis aim to support the formation of judgement and reflection. It is clear, from the described methodological issues with the tools, that a calculative approach would lead the designer astray. Therefore, it is recommended that additional time will be spent on measurement and decision theory to the engineering curriculum. However, this would not solve the whole issues, if the rest of the curriculum still enforces the applied science view on design. It needs larger changes in order to get the engineering student more acquainted with the contextual and underdetermined nature of innovative engineering design practise. Otto and Wood (1999) have suggested to introduce a sequence of design projects during the whole engineering curriculum, starting with (1) reverse engineering of an existing artefact in an introductory design course, via (2) development of an original conceptual design, to (3) designing improvements on the existing artefacts, and finally (4) design and fabricating of a working prototype in a capstone design project. Sheppard (2001) gives a similar suggestion by providing 'engineering problem solving modules' throughout the curriculum to train students in the application of science-based analysis modelling, as well as, back-of-the-envelop calculations or 'engineering estimations' to address engineering questions. Various universities have picked up this concept of introducing design courses early in the curriculum by providing freshman and/or undergraduate level design courses in which the design process and artefacts are studied by case-based learning or dissection analysis. Other universities are introducing design projects, also referred to as cornerstone design projects, at undergraduate level in order to enhance student's motivation, promote retention in engineering, and increase the students practical experience with engineering design work (Dym et al. 2005; Sheppard and Jenison 1996).

While the addition of design projects early into the engineering education seems to address the limited time spent on design skill in the general engineering curriculum, it does not address the gap that exists between the analytical-based courses and the design-type courses. I would like to propose a more integrated solution in which the science courses should also include open-ended, contextual, limited knowledge problem solving as part of their teachings. This is in line with the proposal made by Bucciarelli (2003), in which he argues for the transformation of traditional exercises in engineering science courses, so that they embody the nature of engineering, while at the same time getting across the scientific principles being taught. It should be noted that my suggestion goes a step further than some already existing attempts to simply complement traditional science and engineering science classes with a few open-ended problem solving assignment or 'realistic' cases, while the majority of examples, assignments, and tests are still analytical in nature. Instead the aim is to incorporate the open-ended, contextual, uncertain nature of engineering practice in every aspect of the engineering teaching, such as illustrative examples in lectures, homework assignments, as well as exams. Furthermore, I propose the same integration for the 'soft' courses in the engineering curriculum, such as ethics, communication, business, law, safety, and sustainability. These 'soft' courses traditionally do not discuss the analytical approaches from natural science and engineering science and the implications they have for the perspective of their fields, while for engineering student this would be very fruitful. For example, an ethics course could show were the value-laden trade-offs are hidden when engineers apply thermodynamic and kinetic models to optimise reactor designs. For a true integration of these 'soft' topics, it is needed that also the science and engineering science courses take these topics on-board. The full integration of scientific, design, and 'soft' topics would build an engineering curriculum with courses that have a special focus, but places them in the real context of engineering practice. Such a curriculum would provide the student with the multidisciplinary skills that are vital to a successful academic trained engineer.

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Summary

Innovative engineering design shapes the development of novel technologies and is ethically as well as socially relevant, because it affects what kind of possibilities and consequences will arise. A major challenge in engineering design work on innovative technologies is the multitude of uncertainties in the form of known unknowns, unknown unknowns, complexities, and ambiguities. The evaluation and generation of design concepts are general and essential parts of the design process in which value-laden considerations play a role. In order to contribute to the adequate dealing with social and ethical issues in innovative engineering design practice, this study has focused on the selection of the 'best' design concept taking into account ethical and social issues in the early design stages and the development of ethically and socially acceptable design concepts which are 'robust' with respect to relevant uncertainties.

In the current literature little to no attention has been given to the way ethical and social issues can be addressed in innovative engineering design, therefore, an exploratory research approach has been employed to investigate this unexplored area. In a critical methodological analysis on frequently applied selection tools, it was found that the information availability in innovative design is the main limitation for calculative decision making methods that aim to support judgement formation. The faced uncertainties in engineering design restrict the tools in such a way that they produce incoherent outcomes, if used to choose a winning design concept. In the subsequent exploratory ethnographic studies the practical application of these selection tools was investigated. The results show that the design engineers use decision tools to support their value-laden judgement formation, but that the tool does not prescribe or describe the selection, so avoiding the identified methodological limitations of this kind of tools. In order to consider value-laden design criteria in the evaluation process, design engineers would be assisted by clear performance measures. The results indicate that current index methods, like the Fire and Explosion Index, do not provide adequate measures that are directly applicable in the selection of the 'best' design concept. Still they provide a good starting point to build upon, if practical considerations of innovative engineering design are taken into account.

In a critical literature study, it was investigated what kind of valued laden aspects play a role in the development of design alternatives in the innovative field of nanotechnology. This literature study grounds the investigation into the development of design concepts that are robust with respect to the uncertainties that surround innovative design work. It indicates that approaches for robust and innovative engineering design work require plasticity towards specific applications and time scales of possible effects. Subsequent exploratory ethical inquiry indicates that existing approaches to address social and ethical issues, such as the Twelve Principles of Green Chemistry, can be adapted to new and innovative areas of engineering by abstraction and successive tailoring to the specific application. Design engineers can further be supported in the development of robust designs by approaches that allow for the evaluation of moral acceptability of design concepts under uncertainty. In this thesis it is

shown that the moral acceptability can be evaluated by conceptualising the application of the designed artefact as a social experiment that needs to meet four normative conditions (absence of alternatives, controllability, informed involvement, continuous re-evaluation), and that such an evaluation is fruitful for innovative engineering design.

All in all, it is concluded that design engineers can deal with social and ethical issues under uncertainty that is typical of innovative design by forming design judgement with the help of proper selection tools and development approaches in order to design a robust artefact that is adaptable in its configuration, flexible in its functioning, resilient to design assumptions, and resistant to changing circumstances.

Samenvatting

Innovatief technisch ontwerp ligt aan de basis van technologische ontwikkeling. Dit ontwerptraject is maatschappelijk en ethisch gezien interessant, omdat het zowel de mogelijkheden als de consequenties van deze technologieën beïnvloedt. Een belangrijke uitdaging in de opzet van het technisch ontwerp van innovatieve technologieën is de grote hoeveelheid onzekerheden, in de vorm van zowel bekende als onbekende onbekendes, complexiteiten en dubbelzinnigheden. Het genereren en de evaluatie van ontwerpconcepten zijn algemene en essentiële onderdelen van het ontwerpproces. Hierbij spelen morele overwegingen een belangrijke rol. Om bij te dragen aan een adequate omgang met maatschappelijke en ethische kwesties in de innovatieve ontwerppraktijk heeft dit onderzoek zich gericht op de selectie van het 'beste' ontwerpconcept. Hierbij worden ethische en sociale kwesties meegenomen in het begin van de ontwerpfase en tevens gecombineerd met de ontwikkeling van ethisch en maatschappelijk aanvaardbare ontwerpconcepten die 'robuust' zijn met betrekking tot relevante onzekerheden.

In de huidige literatuur is weinig tot geen aandacht besteed aan de manier waarop ethische en sociale kwesties in innovatief technisch ontwerp kunnen worden aangepakt. Om dit onontgonnen gebied te bestuderen is dan ook een verkennende onderzoeksbenadering gebruikt. In een kritische analyse van vaak toegepaste selectiemethodieken bleek, dat de beschikbaarheid van informatie in de innovatieve ontwerppraktijk de belangrijkste beperking is voor methoden met een calculatieve benadering die zich richten op het ondersteunen van de oordeelsvorming. De bestaande onzekerheden in technisch ontwerp begrenzen deze methoden zodanig, dat ze incoherente resultaten produceren bij inzet voor de keuze van een winnend concept. In de daarop volgende verkennende etnografische studie werd de praktische toepassing van deze selectiemethodes onderzocht. De resultaten laten zien dat ontwerpers selectiemethodes gebruiken ter ondersteuning van hun morele overwegingen, maar dat deze methode niet de definitieve selectie voor hun maakt. Hiermee vermijden zij de geïdentificeerde beperkingen van dergelijke methoden. Om morele ontwerpcriteria in het evaluatieproces mee te nemen zouden ingenieurs gebaat zijn bij duidelijke prestatie-indicatoren. De onderzoeksresultaten geven aan, dat de huidige indexatiemethoden, zoals de Fire and Explosion Index, geen correcte maat geven die rechtstreeks bruikbaar is voor de selectie van het 'beste' ontwerpconcept. Toch bieden ze een goed uitgangspunt om hierop door te bouwen wanneer men rekening wil houden met praktische overwegingen in innovatief technisch ontwerp.

In een kritische literatuurstudie is onderzocht welke morele aspecten een rol spelen in de ontwikkeling van alternatieve ontwerpen in het innovatieve veld van de nanotechnologie. Deze literatuurstudie is de basis voor het onderzoek naar de ontwikkeling van ontwerpconcepten, die robuust zijn met betrekking tot de onzekerheden die innovatief ontwerpen met zich meebrengt. De resultaten geven aan dat plasticiteit ten opzichte van specifieke toepassingen en tijdschalen van mogelijke effecten nodig zijn voor robuust innovatief ontwerp. Het daaropvolgende verkennend ethisch onderzoek wijst

erop dat de bestaande benaderingen voor de aanpak van sociale en ethische kwesties, zoals de Twelve Principles of Green Chemistry, kunnen worden aangepast aan nieuwe en innovatieve velden van technologie door abstractie en daaropvolgende afstemming op een specifiek toepassingsgebied. Ontwerpers kunnen verder in het ontwikkelen van robuuste ontwerpen worden ondersteund door middel van benaderingen die de evaluatie van de morele aanvaardbaarheid van ontwerpconcepten onder onzekerheid mogelijk maken. Dit proefschrift laat zien dat de morele aanvaardbaarheid van het ontworpen artefact kan worden geëvalueerd door de conceptualisering van de toepassing als een sociaal experiment dat moet voldoen aan vier normatieve voorwaarden (afwezigheid van alternatieven, beheersbaarheid, geïnformeerde betrokkenheid, continue her-evaluatie) en dat een dergelijke evaluatie vruchtbaar is voor innovatief technisch ontwerp.

Al met al is de conclusie dat technische ontwerpers kunnen omgaan met sociale en ethische kwesties onder onzekerheid die typisch zijn voor een innovatief ontwerp door de vorming van ontwerpoverwegingen met de hulp van de juiste selectie methode en ontwikkelingsbenaderingen voor een ontwerp van een robuust artefact. Een zo ontworpen robuust artefact beschikt over een aanpasbare configuratie, is flexibel in haar functioneren, is veerkrachtig ten opzichte van ontwerpaannames en bestand tegen veranderende omstandigheden.

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