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The State Department of Toxic Substances Control (DTSC) contracted with the University of California Santa Barbara (UCSB) to research background information on the current state of affairs in chemical alternatives assessment in order to provide a foundation for AA guidelines development. This report identifies and evaluates existing tools, standards, methods and models for assessing and comparing alternatives.

CHEMICAL ALTERNATIVES ANALYSIS: METHODS, MODELS, AND TOOLS

Revised Final Report to the Department of Toxic Substances Control

August 2010

Brandon Kuczenski
Roland Geyer

Bren School of Environmental Science and Management
University of California, Santa Barbara

Chemical Alternatives Analysis: Methods, Models, and Tools Revised Final Report to the Department of Toxic Substances Control

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DTSC Contract #08-T3629
DTSC Manager: Bob Boughton

Brandon Kuczenski
bkuczenski@bren.ucsb.edu

Roland Geyer
geyer@bren.ucsb.edu

Bren Hall
University of California, Santa Barbara
Santa Barbara, CA 93106-5131

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Executive Summary

Chemical Alternatives Analysis (CAA) is an emerging methodology for avoiding harm or potential harm associated with chemicals of known concern. Toxic substances in industrial use can present many dangers to workers who handle the substances, to consumers who may be exposed to them in the products they use, to communities situated near industrial facilities, and to the broader environment in the form of pollution and ecological damage. Increasingly, through shifting public opinion and regulations, companies are compelled to consider the hazards presented by their activities and products. Alternatives analysis provides a deliberative framework for identifying ways to reduce the use of toxic substances and mitigate the risks of harm. Its two main goals are to reduce hazards associated with a particular chemical of concern and to understand the benefits and drawbacks associated with alternative approaches that may reduce or eliminate the need for the chemical of concern.

CAA is an outgrowth of alternatives assessment, the identification and evaluation of a number of alternative ways of accomplishing a goal. Hallmarks of alternatives assessment include the incorporation of both qualitative and quantitative information into a decision, a diminished reliance on the results of risk assessment, a description of the functional use of a chemical as a basis for developing alternatives, and the use of an iterative framework to continually seek safer alternatives. The outcome of an alternatives assessment is a comparison of the alternatives considered to the current system in each of several different categories, such as human health impacts, environmental impacts, and economic feasibility. The results are often presented qualitatively and in a visually immediate form, such as a table with different colors and symbols denoting the results of the comparisons. CAA joins alternatives assessment to a decision process for selecting a course of action that leads to a reduction in toxic threats.

Assembling a large set of potential alternatives is among the most important steps in ensuring a successful alternatives analysis. In the case of chemicals, the simplest alternative is a substitution of one chemical with a less hazardous chemical that fulfills the same purpose. However, 'alternative' can also be defined more broadly to include reformulations, process changes and even product redesigns. Having a wider scope of available options increases the likelihood that a safer alternative will be found; however, it also in-

creases the complexity of the analysis. All alternatives must be considered in depth so that any potentially harmful consequences can be detected. If a potential alternative differs substantially from the base case, then the level of study necessary to understand the consequences of implementing the alternative is expanded proportionately.

Gathering information about alternatives can be the most time-intensive part of CAA. Relevant information includes data about chemical hazard traits, properties and risk profiles as well as information about the product in which the chemical is used. CAA is often conducted in a life cycle perspective, taking into account the entire life cycle of the chemical and the product, from extraction of raw materials to disposal. This may require understanding the supply chain of the product. Pertinent information about the hazard traits associated with different products, as well as the potential benefits and drawbacks of alternatives, should be collected and analyzed to support informed decision making.

Information about the product system and possible alternatives can be used to develop a strategy for transitioning to safer products. Decision-making tools have been developed which aim to elicit the subjective preferences of decision makers and synthesize them with the objective evaluations of alternatives. These tools can incorporate both quantitative measurements, such as functional performance and numerical estimates of risk or cost, and qualitative scores, such as estimates of the presence or level of hazard. These tools enable decision makers to select among alternatives in a robust and transparent way, and to involve stakeholders in decision making where appropriate. Particularly in cases of high public involvement, controversy, or sensitive environmental or social conditions, transparency in decision making is of highest importance. Decision analysis tools can aid in documenting a decision so that the reasoning behind it can be made clear. Parties who disagree then have a basis for discussion and engagement. Here again, iteration and continuous improvement may provide opportunities to make decisions more robust.

For CAA to be an effective route to reducing threats from chemical use, it should be applied widely and routinely by industrial actors who use harmful chemicals. An array of meaningful alternatives must be considered. The analysis should include an investigation of potential impacts throughout each option's life cycle, from raw materials extraction to final disposal. A summary of the hazards evaluated should be reported publicly to promote consumer awareness of hazards and to inspire companies to innovate. Because technology advances and market conditions change, the analysis should be performed in an ongoing fashion, and reports should be updated regularly. CAA should be used in combination with traditional risk mitigation strategies and other routine safety assessments in order to promote a long-term shift to safer products and processes.

About this report

This report was prepared with the objective of identifying and evaluating existing tools, standards, methods and models for assessing and comparing alternatives, focusing on

chemicals of concern in consumer products. Chapter 1 introduces the main concepts surrounding the use of toxic chemicals in the industrial economy and gives an overview of the alternatives analysis process. Chapter 2 reviews significant regulatory frameworks that involve either the evaluation of alternatives or the management of toxic substances. Chapter 3 explores existing models and methodological frameworks for conducting alternatives assessment. Chapter 4 reports a variety of tools and data resources that are useful in evaluating the hazard traits and human and environmental impacts of individual chemical substances. Methods for modeling and documenting complex decisions are presented in Chapter 5. General considerations for performing CAA are discussed in Chapter 6, along with several case studies of published alternatives analyses of harmful chemicals.

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Chapter 1

Introduction

1.1 Safer Products and Toxics Use Reduction

Chemicals are vital for making the products we consume in our daily lives. Chemistry has brought us countless advances in our quality of life, including cheap and ubiquitous polymers, modern agricultural techniques, high technology and unprecedented home convenience. Chemicals are used in all stages of production for processing materials, as additives, and as feedstocks. According to the US EPA's 2006 Inventory Update Report, the US produced or imported 11.8 billion metric tons of chemicals in 2006, comprising some 6,200 chemicals each produced in volumes of 25,000 lbs or more per year (US Environmental Protection Agency, 2008). When chemicals below this threshold are included, the total count of chemicals in commerce in the US numbers more than 80,000.

Some chemical products, as well as chemical waste products and chemical emissions into the environment, have properties which can cause damage to human health or ecosystems. Chemicals are generally regarded as "toxic" if they are associated with an increased incidence of cancer, mutations, reproductive damage, birth defects, disruption of endocrine functions, or other negative effects on humans or animals. In addition to toxics, there are "persistent" chemicals which have a tendency to persist in the environment for long periods of time with unknown effect, and "bio-accumulative" substances which cannot be broken down by metabolic pathways or flushed from the body. Some toxic chemicals have done extraordinary and irreparable damage to human health or to the environment, either due to accidental release or because of a lack of information on adverse effects. Many other substances are suspected, but not known with certainty, to be harmful. There is tremendous uncertainty about the nature or extent of the threats that may be caused by toxic chemicals in the environment. The role of chemical policy is to balance the benefits of chemical use against the costs, encouraging businesses and manufacturers to produce and sell products which improve our lives while regulating the use

of dangerous substances and gaining an understanding of their potential ill effects on humans and the environment.

One of the most successful strategies for reducing the risks associated with toxic chemical exposure is to reduce the use of toxic chemicals in the first place. Toxics use reduction, as part of a larger program of pollution prevention, can be very effective because it reduces risks at all stages of production, from chemical formulation to use and disposal. Toxics use reduction can be attained in many ways: by substituting a less toxic chemical for a mor toxic one, by using a toxic substance in lesser amounts, by reducing exposure to a toxic substance already in use, or by redesigning a product or process so that the chemical of concern is no longer required. Not all of these routes to toxics use reduction may be available in a specific situation.

California's Safer Alternatives Bill (AB 1879, 2008) is an example of toxics use reduction legislation because it aims to reduce the level of hazard presented by toxic materials in the state economy through the development and evaluation of potential alternatives. Achieving this goal for any given chemical of concern requires that two main tasks be accomplished: identifying potential alternatives which reduce exposure to the substance, and assessing the suitability, viability and efficacy of each alternative in order to decide on a course of action. The development of possible alternatives in a given situation is highly dependent on the specific chemical of concern and the product system in which it is used. However, a common set of tools can be used to analyze a list of potential alternatives and choose among them.

The purpose of this report is to describe existing methods, models and tools for evaluating alternatives to chemicals of concern and to place them in a common framework. Individuals and businesses have faced difficult decisions for a very long time, and numerous tools have been developed to support the decision-making process. These tools have evolved into a branch of applied mathematics called decision theory, which includes risk analysis, cost-benefit analysis, expected value theory and other quantitative decision-analysis techniques. These methods are the subject of extensive ongoing study and are not the main focus of this report, but they are discussed in Chapter 5, "Choosing Among Alternatives." This report focuses instead on specific issues surrounding the development of alternatives for toxic chemicals in commerce.

1.2 Life Cycle Thinking

Production of a typical consumer product requires the extraction of resources from the earth, refinement of materials, manufacture of components, assembly into the final product, and distribution, as well as many other support services such as energy production, supplies, chemicals, and transportation. After a consumer is finished with a product, it

may be collected for recycling or disposed, and special care may be required if the product contains hazardous materials. This sequence of production stages is referred to as the "life cycle" of the product. "Life cycle thinking" or a "life cycle perspective" means taking into consideration the full life cycle of the product when evaluating its impacts on health and the environment.

Life cycle thinking is an important part of evaluating the environmental performance of products. Studying the life cycle of a product allows a designer or analyst to:

1. understand the energy, resources, and infrastructure required to make a product;
2. assess the impacts arising from different stages of production and use;
3. find opportunities to improve a product's environmental performance;
4. identify potential regrets that may arise from a change to a product system.

Often the impacts due to any one life cycle stage are small in comparison to the total impact throughout the life cycle. In many product systems, however, one life cycle stage dominates the others. In the life cycle of clothing, for example, the vast majority of impacts come from the use phase, due to repeated washing and drying of clothes (Cullen and Allwood, 2009). Shoes, on the other hand, do not require routine cleaning and generate little impact during the use phase. Thus the life cycle impacts of shoes are thus dominated by pre-consumer phases such as material production (Arcenas et al., 2010).

Making changes in a product system could lead to increased impacts, reduced impacts, or a shifting of impacts or burdens between life cycle stages or between different impact areas. For instance, using washable plastic containers instead of disposable bottles reduces direct resource consumption and solid waste, but requires the production of detergents for cleaning and the use of energy to heat wash water (Franklin Associates, 2009). As another example, treatment of wastewater reduces impacts on freshwater ecology but requires energy production which causes air pollution (Lundin et al., 2000). This could be described as the shifting of some burdens from water to air.

In the context of chemical alternatives assessment, the most important reason for life cycle thinking is to identify potential regrets that may arise from the alternatives under consideration. For instance, in response to the phase-out of lead as an oxygenate in gasoline, refiners increased the use of alternative oxygenates such as methyl tertiary-butyl ether (MTBE). However, this alternative oxygenate is a persistent toxin which contaminates ground water (Office of Environmental Health Hazard Assessment, 1999). When burned in water-going craft with two-stroke engines, MTBE is introduced directly into the water leading to significant contamination. A more careful consideration of the life cycle of fuel oxygenates, particularly with regards to their use in highly polluting two-stroke engines, may have identified MTBE as a regrettable substitution and spurred the development of other options.

Life Cycle Assessment (LCA) is a standardized methodology for evaluating the life cycle impacts of products and services (International Organization for Standardization, 2006). The core of the methodology is a model of industrial production as a network of processes used to produce the product. Each process takes in resources, energy, and materials and outputs a product as well as wastes and emissions. The total resource requirements and emissions associated with a product system can be found by adding up the amounts for all processes in the life cycle. Preparing a comprehensive and accurate LCA can be costly and time-consuming. However, the principles of LCA can be easily adapted as a preliminary tool for life-cycle thinking. LCA is discussed in more detail in Section 3.5.

1.3 The Precautionary Principle

With the rise of the environmental movement in the 1960s and 1970s came the realization that human technological activities can have consequences to human and environmental health that are difficult to predict (Carson, 1962; Russell and Landsberg, 1971). In response to the growing specter of unseen ecological challenges, members of some communities began to argue that responding to visible threats to human and environmental health was inadequate, and that society should aim to prevent potential harm, even in the absence of conclusive scientific data about the level of risk. This notion was first codified in the former West Germany in the late 1970s and early 1980s as Vorsorgeprinzip, and came to be known in English as the Precautionary Principle (Jordan and O'Riordan, 1999).

While there is an abundance of interpretations, two core ideas are common to all statements of the Precautionary Principle (Tickner and Geiser, 2004). First and foremost is the notion that preventive action should be considered even in the absence of conclusive evidence of harm in cases where adverse impacts could be substantial. The second core component, referred to as the "reversed burden of proof," is that proponents of a potentially hazardous activity bear the onus of proof that the activity is safe, rather than regulators or the public being required to prove that it is harmful.

The precautionary principle found broad reception in Europe over the past 40 years. The federal chemical regulatory policies of Sweden are notable for applying the "reversed burden of proof" to the chemical industry as early as 1969 (Lofstedt, 2003). Sweden, along with Germany and six other Northern European nations, made precaution an explicit component of their joint effort to protect the North Sea in 1987 (OSPAR London Declaration, 1987). When the European Union was formed in 1992, the precautionary principle, together with the principle of preventive action, was invoked as the constitutive basis of environmental legislation (Treaty of Maastricht, 1992, Article 130r). The United Nations conference on Environment and Development in Rio de Janeiro in 1992 gave an international mandate for member states to apply "the precautionary approach" to threats of serious or irreversible environmental damage (United Nations Department of Economic and Social Affairs, 1992, Principle 15).

In an effort to advance adoption of the precautionary principle in the US, a group of researchers, regulators, policy experts, and activists convened a meeting at the Wingspread Center in Racine, WI in January of 1998. They published a statement, known now as the Wingspread Statement, in which they declared that the precautionary principle should be adopted by all "corporations, government entities, organizations, communities, scientists and other individuals"; application of the precautionary principle should be "open, informed, and democratic" and must involve "an examination of the full range of alternatives, including no action." (Ashford et al., 1998). The Wingspread statement is among the stronger contemporary formulations of the precautionary principle (Di Salvo and Raymond, 2010).

An important element of the precautionary principle is the distinction between "hazard" and "risk." Hazard can be defined as "the inherent potential of a substance to harm human beings or the environment." The hazard "depends entirely on the properties of a substance." On the other hand, risk is "the likelihood of harm occurring and its possible extent. Sufficiently large exposure of human beings and the environment is required for harm to occur." (Definitions from KEMI, 2007; see section 3.3). While traditional environmental regulation has focused on assessing and managing risk, the precautionary principle asserts that the reduction of hazard is also an important consideration. However, the dominance of the "hazard" viewpoint in discussions of the precautionary principle has softened over recent decades (Di Salvo and Raymond, 2010).

In 2005 the California Office of Environmental Health Hazard Assessment (OEHHA) adopted the following working definition for taking a "precautionary approach" in crafting environmental policy:

> "Precautionary Approach" means taking anticipatory action to protect public health or the environment if a reasonable threat of serious harm exists based upon the best available science and other relevant information, even if absolute and undisputed scientific evidence is not available to assess the exact nature and extent of risk.

1.4 Current Approaches to Toxic Chemicals

1.4.1 Chemical Hazards and the Risk Paradigm

The 1976 Toxic Substances Control Act (TSCA) gave the EPA the authority to regulate the use of toxic substances in commerce. Under the act, the agency may restrict the use of a chemical if it poses "an unreasonable risk of injury" to humans or the environment. Over the decades since the enactment of TSCA, the "risk paradigm" came to be the dominant

mechanism for evaluating the threats posed by chemicals (NRC, 1983; US EPA, 1984). Under the risk paradigm, the likelihood of some harm or injury occurring, as well as the severity of that harm or injury, are estimated and combined to produce an estimate of risk.

Comparative risk assessment (CRA) is a broad term used to represent the comparison of different alternative risk scenarios against one another within a decision analytic framework (Andrews and Apul, 2004). Because the risks associated with different hazards are incommensurable (they cannot be directly compared to one another), some means of eliciting the subjective preferences of decision makers is required to perform CRA effectively. Multi-criteria decision analysis refers to a family of tools which support the decision-making process in situations involving multiple incommensurable quantities (Linkov et al., 2006a).

In the context of toxic substances, risk assessment entails the scientific determination of the levels of chemical exposure which present a tolerable risk of injury. Human health risk assessment considers questions of consumer or occupational exposure to chemicals and is widely used by chemical formulators and manufacturers to evaluate the safety of their products. Ecological risk assessment refers to the application of risk assessment principles to questions of ecological damage, and is primarily performed for the purposes of regulatory compliance (Rand and Zeeman, 1998).

There are four parts to a chemical risk assessment:

1. a hazard trait or property of a substance that could pose a threat;
2. a dose response which describes the relationship between exposure to a substance and an adverse effect;
3. an exposure assessment or exposure scenario which describes the level of exposure that is likely in a given situation;
4. a risk characterization which quantifies the level of risk presented by the scenario being modeled.

According to the risk paradigm, the process of risk assessment is separated from the process of determining whether and how risks should be managed or reduced, referred to as "risk management." Risk management is the practice of maintaining a reasonably low level of risk through technical measures and policy, and is based on the results of risk assessments. Risk managers can use the results of a risk assessment to determine what actions are appropriate under the given level of risk. Actions to be taken depend on the nature of the risk but may involve the use of protective equipment (in the case of occupational exposure), better controls on emissions (in the case of ecological exposure), further processing of products or product redesign to reduce or remove exposure, or many other options.

Risk assessments are subject to different types of uncertainty (Walker et al., 2003). That uncertainty can manifest in quantifying the level of risk (statistical or parametric uncertainty) and in describing the nature of the risk (epistemic uncertainty). In the case of chemicals, parametric uncertainty is involved in three of the four parts mentioned above: in determining the reference dose that produces an adverse effect; in estimating the likely level of exposure; and in computing the risk presented by that exposure. In addition, epistemic uncertainty is present in all four parts: in deciding whether a substance is hazardous, in identifying what potential injuries may result (and thus identifying what responses to look for in estimating dose-response), in capturing possible exposure pathways, and in characterizing the resulting risk (Ramsey, 2009). Other aspects of hazardous chemical exposure are not currently addressed in risk assessment, such as the synergistic effects of multiple chemical stressors (Silva et al., 2002) and controversy in interpreting or applying empirical results (Rudén, 2006). Risk assessments typically represent parametric uncertainty through the use of safety factors meant to represent the maximum potential uncertainty in critical values (Chapman et al., 1998). However, safety factors alone cannot account for uncertainty arising from a lack of fundamental understanding or an incorrect model of the system under study.

The risk paradigm is also controversial for other reasons. Risk assessment is a highly technical process, placing it beyond the reach of the general public and limiting engagement of stakeholders in environmental decisions (Silbergeld, 2002). In addition, and partly as a consequence of its technical nature, analysis of risks includes an implicit judgment of what constitutes a safe or "reasonable" level of risk (Crane and Giddings, 2004; Gregory et al., 2006). The necessary value judgment is often made privately by analysts or regulators, and not necessarily by those impacted by the risk. Some practitioners object to the very notion of assigning numerical value to human or ecological life or wellness, arguing that a risk assessment is in essence used as a license to commit harm (O'Brien, 2000). Finally, certain catastrophic risks, such as species extinction or large-scale catastrophe, challenge rational consideration in any quantitative framework.

Overall, the use of quantitative techniques to assess risk must presume that the analysts' understanding of the world is sufficient to account for all relevant risks and that the risks can be adequately measured by the analytic model in use. This makes risk assessment a valuable analytic tool for a specific circumstance: for modeling the effects of a substance with known hazard properties in a specific exposure scenario. Its utility is considerably reduced in situations with large knowledge gaps. However, because of its importance in many pieces of legislation regarding chemical safety, risk assessment is likely to maintain its dominant role in the future.

1.4.2 Green Chemistry

Many developments which have improved the standard of living in the modern age can be traced to advances in chemistry. At the same time, chemicals have been at the core of

some of the most visible environmental catastrophes of the last 50 years. Even under safe conditions, chemical production accounts for a substantial share of energy and resource consumption in industrial nations and generates hazardous waste. Green chemistry developed as a pro-active response to the environmental and health hazards posed by the ubiquity of chemicals in modern industry. Green chemistry was developed by the US EPA in the early 1990s and was formalized in the 1998 textbook "Green Chemistry – Theory and Practice" (Anastas and Warner, 1998). In it, the authors identified twelve principles which can be applied at the design stage of chemical processes, resulting in improvements to the safety and resource efficiency of operations. These principles include general notions such as design with less-toxic substances, prevention rather than clean-up of waste, and energy efficiency, as well as more technical considerations such as atom economy (minimizing the use of intermediate molecules which do not get incorporated into final products) and use of catalysts (which are reused) instead of reagents (which are consumed).

Since its inception, green chemistry has grown into a full-fledged field of inquiry with its own journal (Green Chemistry, published by the Royal Society of Chemistry) as well as numerous institutes, centers and research efforts. Green chemistry is recognized to be an integral part of the pursuit for sustainable engineering with both environmental and economic benefits (Kidwai, 2006; Tucker, 2006). If conceived and implemented with a precautionary mindset, green chemistry may contribute to a substantial reduction in the hazards posed by industrial chemistry (Thornton, 2001; Marteel et al., 2003).

The nature of green chemistry as a design tool distinguishes it from evaluation tools such as risk assessment. Applying the principles of green chemistry requires at least some control over the materials and manufacturing processes used to create a product, placing it outside the scope of activity of many retailers.

1.4.3 Alternatives Assessment

Alternatives assessment is the systematic analysis of a range of different options for accomplishing the same goal (O'Brien, 1999). Instead of evaluating the acceptability of a specific action plan, analysts are directed to consider the variety of approaches that might exist. By framing the question around the specific goal and searching for meaningful choices to accomplish it, alternatives assessment provides a mechanism for open and deliberative analysis of hazards and consequences. Proponents describe alternatives assessment as being solution-oriented, in comparison to conventional environmental regulation being problem-oriented, because the process relies on identifying a set of viable options (Tickner and Geiser, 2004). Once the possible solutions are identified, their relative performance against a set of criteria can be evaluated. The criteria for evaluation should include the presence of hazards as well as technical performance and assessment of risks and costs (Rossi et al., 2006). The favored alternative can be selected as the choice with the greatest avoidance of hazards which still feasibly accomplishes the goal.

Alternatives assessment thus operationalizes the precautionary principle by giving stakeholders a definite means to identify the path with a lower potential to harm. However, by no means does choosing an alternative approach ensure that hazards are reduced. Different options still need to be considered in detail to determine their likely benefits and drawbacks. Additionally, the quality of the assessment is constrained by the alternatives under consideration. A crucial aspect to the success of alternatives assessment is the inclusion of a broad range of alternative choices. The collection of alternatives should include "alternative approaches" as well as merely "alternative designs" (Steinemann, 2001) and should also include the "no action" alternative: to not perform the activity at all. One way to ensure a greater breadth of meaningful choices is to involve a larger number of stakeholders, including the general public where appropriate, as early as possible in the deliberative process (O'Brien, 2000; Steinemann, 2001).

While proponents of alternatives assessment tend to be critical of risk assessment as it is currently performed, there is no intrinsic philosophical conflict between the two approaches (Chapman, 1999). The constitutive advantages of alternatives assessment are its fundamental focus on achieving a particular end functionality or service, and its reticence to reduce problems to quantitative terms. The outcome of an alternatives assessment, at minimum, should be an array of alternative means to achieve the desired end. Distinguishing the ideal choice among the alternatives is still a decision process which could be clarified through the use of decision-analysis methods. The expected benefits of engaging in an alternatives assessment are (i) a broader array of potential alternatives, including those still in development or not yet feasible (Ashford, 2000), (ii) a broader perspective of potential risks, and (iii) knowledge of opportunities to avoid hazards, rather than merely reduce risks. Alternatives assessment still suffers from many of the same pitfalls as risk assessment, namely a lack of certainty regarding environmental performance and the potential failure to consider significant risks which may not be apparent. However, the emphasis on hazards promotes a precautionary attitude which may lead to the development of safer alternatives that would not have come about under a risk-based paradigm.

1.5 Chemical Alternatives Analysis

Chemical Alternatives Analysis (CAA) is the practice of evaluating the use of a problematic chemical or substance in order to develop ways to avoid its harmful effects. While alternatives analysis can be performed to study alternatives to any given activity, this report focuses on alternatives analysis aimed specifically at reducing the hazards arising from toxic substances. CAA is conducted in the context of a set of chemicals of concern used in a particular product system. While numerous techniques exist to evaluate the performance of a product system, its associated risks and benefits, resource requirements, and environmental impacts, the purpose of a CAA is to compare the performance of an existing product system with one or several alternative approaches that achieve the same

goal. In an alternatives analysis, economic considerations have equal footing with non-economic considerations. CAA is a "big-picture" analysis, meant to integrate the results and findings of many focused studies, such as risk assessments or life cycle assessment, into a comprehensive picture which can aid in decision making.

The development and analysis of alternatives is based on an understanding of the function or performance of the product system under study. In CAA, it is necessary to understand the role of the chemical of concern in accomplishing this function. Once its "functional use" is understood, it is possible to imagine alternative approaches which achieve the same function while reducing toxic threats. One straightforward way to reduce the risk posed by a toxic chemical is to stop using it; therefore one of the simplest alternatives that could be considered is the direct substitution of a less-toxic or non-toxic chemical in place of the chemical of concern. A broader set of alternatives could also be considered, encompassing product reformulations, changes in process or in substance management, and product redesigns which reduce or eliminate the need for the chemical of concern.

The nature and extent of threats posed by toxic chemicals is shrouded in uncertainty, and there are large gaps in our knowledge and understanding of the harmful effects of chemicals. CAA should thus be thought of as an example of a "precautionary approach" under current California policy, intended to reduce known risks and also forestall any predictable but uncertain threats that are likely to arise from a product's production and use. The overarching purpose of CAA is to attain an understanding of the consequences of a product system in order to support intelligent decision making.

If a safer alternative is found, product analysts must make a decision about whether and how to adopt it. Because the potential alternatives may be superior to the existing system in some areas but not in others, making a selection may be challenging. Choosing among alternatives which involve trade-offs among multiple decision criteria is an inherently subjective process which depends on the values and preferences of the decision makers. Because the impacts of toxic chemicals are felt by a broad range of stakeholders in the public, it is important for the decision making process to be transparent and robust, and it is desirable that a wide array of stakeholders be involved (National Research Council, 1996; Murdock and Sexton, 2002).

Chapter 2

Regulation of Toxics and Alternatives

Studies evaluating the feasibility and relative benefits of alternative approaches are common. Companies and public agencies often perform studies such as comparative risk assessments, cost-benefit analyses, or environmental impact assessments to gain an improved understanding of their products and activities. These studies are often internal and driven by economic considerations. Companies are now increasingly including non-economic considerations, such as threats to public health or risks to ecological systems or endangered species, in their assessments of ongoing or potential activities. Often the consideration of these effects is motivated in part by state or federal regulations. It is also increasingly common for companies to assign economic value to their environmental performance in the form of public image or marketability. However, in many cases the external impacts of a company's activities are not captured in the course of a strictly economic or regulatory analysis. Toxic substances in particular can have effects that are difficult to quantify economically.

Alternatives analysis developed in part as a way to allow public and private agencies to gain a fuller understanding of their potential options than traditional assessments provide. CAA in particular is intended to facilitate the search for ways to reduce hazards and risks associated with toxic chemicals while avoiding regrets. In this chapter we detail some significant regulatory frameworks that are relevant to CAA. The chapter begins with the National Environmental Policy Act of 1969 and California's analog, the California Environmental Quality Act of 1970. While not dealing explicitly with toxic chemicals, these acts are significant for the role they played in establishing alternatives assessment as a routine tool. Next, relevant legislation regarding the use and disposal of toxic substances is discussed, including the US Toxic Substances Control Act (1976), California's Safe Drinking Water and Toxic Enforcement Act (1986, known as Proposition 65) and Hazardous Waste Source Reduction and Management Review Act (1989), and Massachusetts' Toxics Use Reduction Act (1989). The chapter ends with an examination of the use of al-

ternatives analysis in Europe's newly enacted Registration, Evaluation, Authorization and Restriction of Chemicals program (known as REACH).

2.1 NEPA and CEQA

Assessment of competing alternatives first gained widespread currency as an environmental problem-solving methodology in 1970 after the National Environmental Policy Act (NEPA) was signed into law by Richard Nixon. NEPA established procedural requirements mandating that an Environmental Impact Assessment be performed for any federal action that was likely to have environmental impacts. The rule is a condition for funding the action and applies to all agencies of the executive branch of the federal government. Shortly thereafter, California passed the California Environmental Quality Act (CEQA), which applied similar requirements to CA state agencies. Significantly, CEQA extended requirements to private activities which require agency approval, subjecting almost any land-use action to environmental assessment (14 CCR 15002 (b)).

A core component of NEPA is the consideration of "the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment" (40 CFR 1502.1). CEQA also made explicit the requirement to consider alternatives, and further required that the state agency not approve any project for which feasible alternatives exist which have less of an impact (14 CCR 15021(a)(2)). Although alternatives assessment is a mandatory part of both NEPA and CEQA, the laws are vague about what exactly constitutes an alternative and how it should be assessed.

The exact nature of alternatives assessment in environmental impact studies prepared for CEQA has evolved through a long and sometimes acrimonious process of precedent and litigation (cf California AEP, 2009). Generally, agencies are not required to be comprehensive nor unreasonably precise, but competent and thorough. Impacts to be considered include "relevant specifics of the area, the resources involved, physical changes, alterations to ecological systems, and changes induced in population distribution, population concentration, the human use of the land (including commercial and residential development), health and safety problems caused by the physical changes, and other aspects of the resource base such as water, historical resources, scenic quality, and public services." (14 CCR 15126.2 (a)) The alternative of "no action" must always be considered. The review should focus on "significant" impacts, "feasible" mitigation options and "reasonable" alternatives which still meet the project's basic objectives.

In practice, alternatives assessments for NEPA and CEQA typically include the proposed project, a reduced form of the proposed project, an alternative project which may bear little resemblance to the proposed project, and the no-action alternative. Other alternatives may also be considered. All alternatives are evaluated on the same basis and the results

are compared directly. No statistics are available on the number of projects which are approved, rejected, or for which alternatives are approved. Environmental impact statements for CEQA are often prepared by private agencies which specialize in preparing such statements. The California Association of Environmental Professionals serves as a trade organization to these agencies and practitioners and publishes an interpretive guide to the regulations, including a recounting of significant legal findings and precedents each year (California AEP, 2009).

NEPA and CEQA demonstrate that alternatives assessment is already well-regarded as a principle for evaluating the environmental soundness of productive activities. However, their implementation carries many pitfalls. In particular, the vague nature of the legal specifications for alternatives assessment has led to a highly litigious environment. NEPA and CEQA alternatives assessments have been critiqued as being too friendly to project proposers, subject to manipulation, and insufficiently democratic (Shepherd and Bowler, 1997; Steinemann, 2001). The alternatives considered may not represent the full breadth of alternatives available, and it is questionable whether the participants have any interest in adopting alternative proposals. Nonetheless, both NEPA and CEQA have contributed to the development of an environmental sensitivity throughout the development community (Clark and Canter, 1997). The framework developed for NEPA and CEQA serves primarily as an exemplar of alternatives assessment in action, but it can also be viewed as a caution against potential failings of later frameworks in which legal outcomes are dependent on the consideration of alternatives.

2.2 Federal Toxics Legislation

2.2.1 The Toxic Substances Control Act (TSCA)

The Toxic Substances Control Act (TSCA), passed in 1976, established a regulatory program for chemicals in the United States. TSCA was critically reviewed by the Government Accountability Office in 1994 and again in 2005 (Government Accountability Office, 1994, 2005). Under TSCA, the universe of chemicals was divided into two groups: existing chemicals already in commerce at the time the law went into effect, and new chemicals. The EPA can review the risks associated with existing chemicals on a case by case basis, but it is not required to perform these reviews. New chemicals are subject to EPA review before entering production. If the EPA finds an unreasonable risk of injury to humans or the environment, or unreasonably high chances of exposure, it can seek a court injunction to halt production. Industrial actors can be compelled to perform additional tests if regulators find that current data are insufficient and that there may be unreasonable risk of exposure or harm.

The GAO report found that the EPA lacks adequate data to review accurately the hazards presented by most new chemicals. Numerous observers (Applegate, 1991; Koch and Ash-

ford, 2006; Wilson and Schwarzman, 2009) have also concluded that TSCA has not produced an effective regulatory regime. The main reason for this is the undue burden on the EPA to demonstrate risk. In order to require that companies perform testing on existing chemicals, the EPA must first show fairly conclusively that unreasonable risk of harm exists, which can be difficult to do in the absence of toxicity data. Between 1979 and 2005, the EPA has reviewed fewer than 200 of the 62,000 existing chemicals in commerce when the law was passed. These reviews have resulted in bans or limits on production of only five chemicals or chemical classes in that period. The asymmetry between new and existing chemicals policy may lead to a condition in which existing chemicals are preferred by industry over potentially safer alternatives which would be subject to more stringent review (Wilson and Schwarzman, 2009).

The EPA's ability to share hazard information with state environmental agencies and the public is also sharply limited by industry claims of confidentiality and trade secrets. Although these claims can be contested, the process for doing so is costly. This reduces the scope of TSCA and limits its potential to increase public knowledge of risks. Confidentiality of hazard information also leads to the duplication of effort in cases where multiple organizations or agencies must assess the characteristics of a given substance independently.

The shortcomings of TSCA are largely matched by the ambitions of the Wingspread Statement: that something less than conclusive proof of unreasonable risk of harm may be sufficient to justify regulation, and that the burden of proof should lie with the proponent, rather than the opponent, of a potentially hazardous activity. An important aspect of the precautionary approach is the avoidance of risk assessment methods in determining *whether* a specific chemical should be regulated, because relying on risk assessment results may delay or hinder the implementation of prudent risk reduction measures (Koch and Ashford, 2006). Alternatives-based regulation highlights known hazard traits and the existence of risks rather than their precise characterization, and thus has the potential to escape some of the failings of TSCA.

Confidential business information presents a challenge to any toxic chemicals regulation. An important aspect of alternatives analysis for chemicals regulation is the dissemination of information on potential exposure to harm, and potential ways to avoid harm, to a critical public, and this should be a core component of any alternatives-based toxics reduction regulation. Furthermore, regulations should specify clearly what kinds of information may be subject to claims of confidentiality, and what kinds of information may not ever be subject to claims of confidentiality. Clarity of the regulations may result in far reduced litigation pertaining to confidential business information (Government Accountability Office, 1994).

2.2.2 The Emergency Planning and Community Right to Know Act (EPCRA)

EPCRA was passed in 1986 in the wake of a disastrous 1984 release of methyl isocyanate from a Union Carbide plant near Bhopal, India, and a smaller release from another plant in Virginia a year later (Neumann, 1998). EPCRA established the Toxics Release Inventory (TRI), a publicly accessible database of toxic substances released into the environment from industrial facilities. The EPA maintains a list of chemicals (581 individual chemicals, plus 30 chemical classes, in 2009) for which environmental releases must be reported. Facility operators are required to report both routine and unplanned emissions if they use any substance on the TRI list in excess of 10,000 pounds per year, or if they manufacture any TRI substance in excess of 25,000 pounds per year. The objective of EPCRA was to increase public knowledge of toxic substances in their communities, thereby pressuring companies to reduce the use of those chemicals or reform their practices.

TRI is widely regarded as a successful program (Fung and O'Rourke, 2000). Over the first twenty years the law was in effect, total releases were reduced 64%, from over 3 billion pounds to about 1.06 billion pounds (US Environmental Protection Agency, 2009). Since its inception, the TRI has been used extensively in governmental, commercial and academic studies of the impacts of chemical releases on public and ecosystem health, and has also provided valuable strategic information to businesses in improving and communicating their environmental performance (Toxics Release Inventory Program, 2003). The TRI database is available on the Internet, and development of new strategies for presenting the information to the public is ongoing, and online tools have been designed for displaying TRI data in a geographic context (see Section 4.1.6). Some state agencies have supplemented TRI data with their own efforts, including statewide databases of chemical releases (TURA; see Section 2.3.3) or collections of datasheets describing chemical properties (New Jersey Department of Health and Senior Services, 2010).

The database also has limitations. Because the reporting criterion is based solely on weight, it does not distinguish among chemicals with varying levels of toxicity (Neumann, 1998). Some toxic chemicals are not included in the TRI list. The database itself does not provide any information on the harmful properties of the substances it tracks, leaving members of the public to conduct their own investigations to understand the significance of TRI data. It is difficult to validate the accuracy of TRI reports, and under-reporting is probably common (Natan and Miller, 1998). In addition, the comparatively high thresholds for reporting may result in significant unreported emissions (Bennear, 2008). The observed emission reductions are a combination of true reductions and reductions in reporting that result from industry reaction to sometimes capricious public pressure, often focused on the largest or most prominent polluters (Fung and O'Rourke, 2000).

2.3 State Efforts

2.3.1 California – Proposition 65

One of the earliest state efforts to supplement federal toxic chemicals policy came from California's voters when they approved the Safe Drinking Water and Toxic Enforcement Act of 1986, known as Proposition 65. The proposition, which was approved by 63% of voters, declared citizens' right to be informed of their exposure to substances known to be toxic. The act established a list of substances known to the state of California to be carcinogens or reproductive toxicants, prohibited the discharge of any listed chemical into drinking water, and required that businesses provide warnings before exposing members of the public to listed chemicals. Only exposures which carry "no significant risk" are exempt. The warning provision takes effect even if safe levels of exposure are not established for a given chemical (Rechtschaffen, 1996).

Proposition 65 was a notable innovation in US chemicals policy for a number of reasons. First, it built upon a growing movement emphasizing the public's "right to know," most clearly illustrated by EPCRA (see Section 2.2.2), rather than relying on "command-and-control" regulatory actions by centralized authorities (Pease, 1991). The proposition did not specify an enforcement mechanism, leaving enforcement of the provisions to the public and the courts, further empowering the public. Second, it shifted the burden of proof to industry to demonstrate that it was exempt from warning requirements (CA HSC 25249.10(c)). In cases where no safe exposure level was established scientifically, it would be difficult for businesses to demonstrate they were exempt from the labeling requirements (Rechtschaffen, 1996). Finally, the regulations required businesses to consider what exposures "may foreseeably occur" (22 CCR 12601(d)). Thus it is inherently precautionary.

The proposition has been controversial (Rechtschaffen, 1996; Barsa, 1997). The warning requirement was not clearly defined by the statute and was judged onerous by business owners. The proliferation of warnings may have diluted their effectiveness. Citizens presented with a warning may not know how to respond to it if they lack information about the nature of the risk or in the absence of alternatives. Finally, businesses may choose to apply warnings in cases where there is not a likelihood of exposure in order to "be on the safe side." However, the proposition brought into the open the use of a growing list of known toxicants, empowering the residents of California to seek their own alternatives.

2.3.2 California – Hazardous Waste Source Reduction

In 1989 the California legislature passed the Hazardous Waste Source Reduction and Management Review Act, known as SB 14, with the aim of reducing the generation of hazardous wastes, reducing the release of chemicals with adverse effects into the environ-

ment, and documenting the management of hazardous wastes in the state (Office of Pollution Prevention and Technology Development, 2006). The law requires generators of hazardous wastes in excess of 12,000 kg per year, or generators of statutorily defined "extremely hazardous wastes" in excess of 12 kg per year, to prepare documents which describe a program for source reduction of hazardous waste. The documents must be prepared every four years. In addition, every two years the Department of Toxic Substances Control is required to review the hazardous waste management practices of at least two California industries and report on its findings. The law was amended by SB 1916 in 1998 to unify and augment the department's source reduction efforts.

Hazardous waste generators must prepare a source reduction program which includes a forward-looking plan, a retrospective performance evaluation and a summary progress report (Office of Pollution Prevention and Technology Development, 2006). Certain small businesses can opt for a streamlined set of requirements. Source reduction measures may include a reduction in use of materials or feedstock that lead to hazardous waste, operational improvements such as loss prevention or improved maintenance operations, process changes, product reformulations, or administrative changes. Generators are encouraged by guidance documents to consider green chemistry principles and practices.

The effectiveness of SB 14 is difficult to gauge because the regulations did not establish a framework for evaluating compliance on a statewide basis. Review of these documents shows that the legislation has had mixed results, with some hazardous wastes being reduced and others increasing (cf. Briones, 2006; Phelps, 2009). These reports give a limited picture of the effectiveness of the bill because they consider only specific establishments in selected industries and do not evaluate the full scale of industrial activity in the state. SB 14 appears to have encouraged hazardous waste generators to assess their practices on an ongoing basis, but the efficacy of the regulation at reducing hazardous wastes through source reduction remains inconclusive.

2.3.3 Massachusetts – The Toxics Use Reduction Act (TURA)

In 1989 The Commonwealth of Massachusetts implemented the Toxics Use Reduction Act (TURA), a sweeping law to reform the oversight of toxic substance use in the state. The law aimed to reduce emissions of toxic substances into the environment by 50% over eight years through voluntary toxics use reduction (TUR) projects. It was also intended to promote the shift away from toxic substances and towards pollution prevention while maintaining economic competitiveness. The Toxics Use Reduction Institute (TURI) was established at the University of Massachusetts, Lowell, to implement the goals of the Act. The Act also created the Office of Technical Assistance and Technology (OTA) within the Massachusetts Executive office of Energy and Environmental Affairs. The mission of the OTA is to provide confidential technical support and consulting services to Massachusetts businesses operating TUR projects. Finally, the Act created a toxic use inventory

for the state of Massachusetts, modeled after the federal Toxics Release Inventory (see Section 4.1.6) but focusing on use rather than emissions of toxic substances.

The law adopts the lists maintained by the federal Toxic Release Inventory (TRI) and the Comprehensive Environmental Response and Compensation Liability Act (CERCLA) in order to identify over 1,400 toxic chemicals of concern. Businesses using these toxic chemicals above a threshold level must (i) prepare a "toxics use reduction plan" in which they describe their use of the chemicals and evaluate their options for reduction, and (ii) report the quantities of the chemicals used, generated as waste, and shipped to customers. If companies reduce their use below threshold levels, they are freed from reporting obligations. The chemical use data is made publicly available on the Internet via TURAData, a Massachusetts-specific analog to TRI. However, it provides more complete data than TRI because TURAData encompasses both use and release of chemicals, while TRI only tracks information on environmental releases.

The law was and continues to be successful, with a 41% reduction in total use of toxics and a 90% reduction in toxic releases since 1990 (http://turadata.turi.org/Success/ResultsToDate.html). The OTA has provided technical assistance to dozens of area businesses on implementation of specific projects, such as changing to aqueous from petroleum-based surface cleaners, eliminating perchloroethylene in dry-cleaning facilities, recycling coolant in industrial machines, eliminating or reducing lead in cable insulation applications, and many others.

TURA and TURI provide an easily accessible and popular approach to encouraging the adoption of green chemistry principles. By adopting lists maintained by the federal government, they sidestep the question of how to identify chemicals of concern. By requiring companies to prepare their own work plans for reducing toxics, the act avoids creating overly specific or unduly constraining regulations. Their comparatively high de minimis levels (25,000 pounds per year for manufacturers or 10,000 pounds per year for users of toxics) reduce the burden on small businesses and reduce the scope of work for the state agency. However, those same high levels mean that chemicals which are toxic in trace amounts may not appear at all on public reports.

From an environmental perspective, these benefits become weaknesses because they reduce the scope of the program. Drawbacks of the TURA approach include the inflexibility of the list of chemicals of concern, omission of small emitters, and a heavy dependence on the public agency to provide technical assistance. The voluntary nature of the regulations may reduce participation by industry in comparison to mandatory measures. Finally, information about hazards and risks associated with given chemicals is not included in the scope of the regulation. Instead, the TURI website uses a third-party source for hazard information (http://www.scorecard.org; see Section 4.1.9). Actions by the OTA are inherently on a case-by-case basis, limiting their scope.

2.4 Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH)

REACH, Europe's flagship chemical regulation program, acquired the force of law in June 2007, beginning an eleven-year period of phase-in (European Commission, 2007). Its primary requirements are that all chemicals in use be registered and evaluated for safety, and that the manufacturers or importers of chemicals must determine and report the hazards and risks associated with the chemicals. The regulations apply to manufacturers or importers of any chemicals produced in excess of 1 ton per year and sold as products. Producers or importers of manufactured goods containing chemicals are also subject to the regulations, though chemicals present at concentrations below 0.1% by weight are exempt. The timeline for enactment of the registration requirements is shown in Figure 2.1.

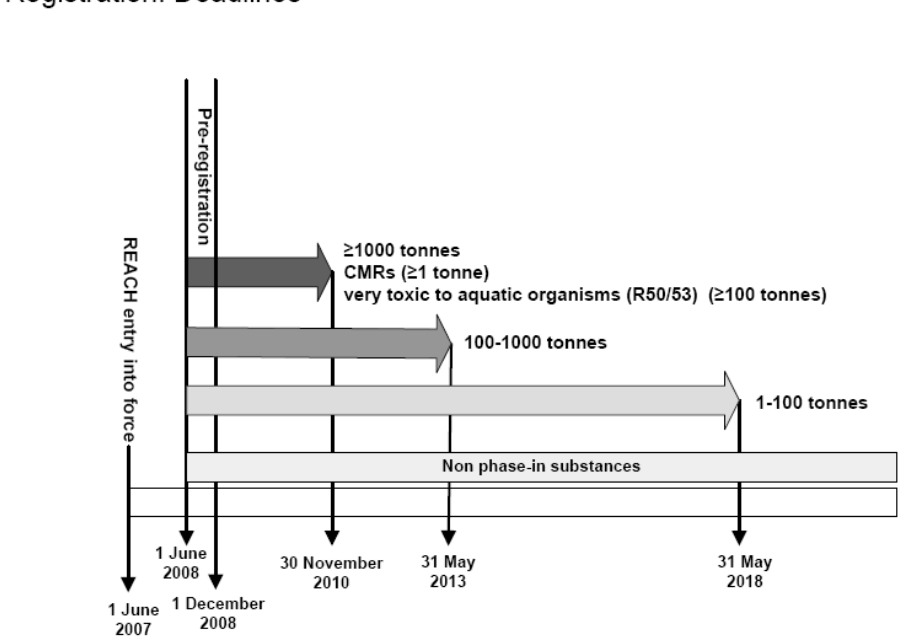
Registration entails submission of a technical dossier describing the chemical's characteristics. In addition, a chemical safety report (CSR) describing hazards and risk classification must be prepared for substances produced in excess of 10 tons per year. The CSR should include information on recommended risk management practices when handling the chemical. Manufacturers are expected to perform laboratory tests to determine chemical properties and hazard characteristics, although quantitative modeling (such as quantitative structure-activity relationships or Q-SAR) and "read-across" can substitute for laboratory testing in some situations. "Read-across" refers to the estimation of one substance's qualities based on the known qualities of similar substances (EU, 2006, Art. 13). In order to reduce costs, multiple registrants of the same chemical are required to submit information jointly, though there are provisions to opt out of joint submission. The registrant that performs the testing is entitled to remuneration from the other registrants. The European Chemical Authority (ECHA) is responsible for reviewing and evaluating the dossiers submitted by the registrants. ECHA can also pursue monitoring and enforcement actions in order to ensure that recommended risk management practices delineated in CSRs are being followed.

The results of chemical testing are to be shared with the explicit purpose to reduce redundant tests, particularly tests on vertebrate animals. In addition, safety data is to be made available throughout the supply chain, including upstream manufacturers and downstream consumers. This requirement applies to information about "health, safety and environmental properties, risks and risk management measures" (European Commission, 2007, 10), but excludes commercially sensitive information. Some information on chemicals is made available to the public by the European Chemicals Agency, but confidential information is excluded.

2.4.1 Annex XIV – Authorization

Annex XIV, the "Authorization List," includes a list of substances whose use must be authorized by the Agency on a case-by-case basis before they may be produced or imported.

Figure 2.1: The timeline for enactment of REACH's Registration requirements (European Commission, 2007)



Annex XIV is meant to include high-priority carcinogens, mutagens, or reproductive toxins (CMRs); persistent, bio-accumulative and toxic (PBT) substances; very persistent and very bio-accumulative (vPvB) substances; and substances presenting an equivalent level of concern to these chemical classes. If a registrant wishes to use an Annex XIV chemical, it is required to demonstrate the capacity for "adequate control" of the substance in question. Failing that, it must "analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution" (EU 2006, Art. 55; see below). If a suitable alternative is found, the registrant is also required to present a substitution plan by which use of the Annex XIV chemical will be phased out. Authorization is a possibility only after demonstrating that use of the chemical provides social and economic benefits that could not be obtained through a substitute.

At the time REACH went into effect, Annex XIV was empty. Chemical regulators from EU Member States can petition for substances to be identified as "substances of very high concern" and listed in Annex XIV of the regulations (See discussion on Annex XV, below). If such a petition is accepted, the substance is added to a "candidate list" for authorization. ECHA prioritizes the chemicals in the candidate list and submits its recommendations for addition to Annex XIV to the European Commission. As of August 2010, seven substances were identified as candidates for inclusion in Annex XIV, but none has yet been officially included. ECHA is awaiting a decision from the European Commission regarding the inclusion of priority substances from this list in Annex XIV.

2.4.2 Alternatives Assessment for Substances of Very High Concern

Substances of very high concern, listed in Annex XIV of the regulations, may only be used if the use is authorized by ECHA. According to the regulations, substances of very high concern (SVHC) are to be "progressively replaced by suitable alternative substances or technologies where these are economically and technically viable." Companies submitting an application for authorization are required to submit an analysis of the alternatives to using the chemical, including a description of their risks and a discussion of their technical and economic feasibility. If a suitable alternative is found, the company must submit a substitution plan that includes a timetable for adopting the alternative. The regulations are not specific regarding the makeup of an alternatives assessment or the necessary components of a substitution plan.

The ECHA has not finalized or published its guidance document that advises companies on how to prepare authorization applications. Presumably this document will describe the requisite components of an alternatives assessment and a substitution plan. At the present time there are no chemicals identified in Annex XIV, and so there are no real circumstances under which a registrant would be required to perform an alternatives assessment.

2.4.3 Annex XV and Annex XVII – Restrictions on Use

Annex XVII comprises a list of restrictions on the use, manufacture, or importing of dangerous substances, preparations, and articles. EU Member States can petition for a specific substance or use of a substance to be restricted if they believe the use presents an unreasonable risk that is not addressed by the risk management practices described in the chemical safety report (CSR). For instance, synergistic exposure may not be handled well by risk management practices.

Annex XV describes the process by which member state competent authorities (MS CA) can petition for the inclusion of new substances, preparations, or uses in Annex XVII. An MS CA may submit an Annex XV dossier to the European Chemicals Agency (ECHA) for one of three reasons:

- To request that a substance be identified for harmonized classification and labeling as a carcinogen, mutagen, reproductive toxin (CMR), or respiratory sensitizer.
- To request that a substance be included in Annex XIV because it is persistent, bio-accumulative and toxic (PBT), very persistent and very bio-accumulative (vPvB), a high priority CMR, or because it presents an equivalent level of concern. Commercial uses of Annex XIV substances must be authorized by the Agency (see above).
- To request that new restrictions be placed on the use of a substance in Annex XVII. The MS CA is required to report on potential alternatives to the substance.

Annex XV dossiers may be submitted for purely bureaucratic reasons (i.e. if clear evidence has already established that a chemical falls into a regulated group that deserves labeling or authorization), or if a member state competent authority would like to submit evidence that clarifies a substance's status, to demonstrate scientific evidence for probable serious effects on human health or the environment, or to dispute evidence to the contrary for a given chemical. In all cases, dossiers should be based on scientific data. Annex XV should only be used when the MS CA can show that action by the full European Community (rather than just the member state submitting the proposal) is appropriate.

2.4.4 Alternatives Assessment for Novel Restrictions

In the case where an MS CA is proposing new restrictions on the use of a chemical, the dossier must include an alternatives assessment in order "to provide information for the analysis of whether the equivalent function provided by the substance can be obtained by other substances or techniques and for assessing the net impact of the proposed restriction to the human health and the environment." The purpose of the alternatives assessment is to guide the Agency in crafting a "proportionate" restriction. Thus, "alternatives" include alternative techniques that may reduce the amount of the restricted substance without eliminating it completely. Guidance for authorities on Alternatives Assessment can be found in ECHA (2007, 68-74).

The specific details of this requirement are manifestly similar to the recommendations made in other alternatives assessment models. Specifically, the assessment should include:

- Description of the use and function of the substance;
- Identification of technically feasible alternatives fulfilling the function(s);
- Assessment of availability of alternatives;
- Assessment of human health and environmental risks related to the alternatives;
- Assessment of economical feasibility of alternatives.

The level of detail included is left to the discretion of the MS CA preparing the dossier. Human health and environmental risks must be evaluated for all alternatives; however, the guidance does not specifically mention consideration of life-cycle impacts or impacts elsewhere in the production chain. Alternatives assessment remains an inherently comparative process. The recommended form for reporting the results of an alternatives assessment is a table in which the base case and the several alternatives are compared qualitatively for each category of assessment.

Petitioning authorities are also invited, but not required, to prepare a Socio Economic Analysis (SEA), which amounts to a more rigorous and extended investigation of the impacts of the change. In addition to the evaluation of technical alternatives to the chemical, the SEA can include impacts on the regulated industry, on other actors in the supply chain, on consumers, on the employment outlook, on economic development, or on "any other issue that is considered to be relevant by an interested party." (European Chemicals Agency, 2008). While further reaching than the alternatives assessment required in Annex XV, the SEA is largely intended to consider economic impacts. Life-cycle environmental impacts, while they could be included, are not explicitly discussed in the regulations or guidance.

2.4.5 Interpretation

Fundamentally, REACH is built on the familiar foundation of quantitative risk assessment that guides much US regulation (Government Accountability Office, 2007). However, it offers constitutive advantages over the US status quo: it centralizes the collection and distribution of chemical information while decentralizing the problem of risk analysis. This decentralization happens in two distinct ways. First, manufacturers and importers are required to perform risk assessments and to report on best practices for risk management on a case-by-case basis. This will likely have the effect of greatly increasing the amount of risk and hazard information available regarding chemicals in commerce. Second, while evaluation of chemical information is managed by a central agency, namely ECHA, the evaluation of specific chemicals is distributed among the EU member states, thus multiplying the capacity of chemical authorities to handle incoming information and eliminating redundancy. Finally, the development of a large, publicly available information infrastructure for managing and distributing risk and hazard data will likely provide benefits far beyond the European Union.

The explicit requirement of manufacturers and importers to provide chemical safety data represents an internalization of the cost of safety assessment to the production of chemicals, enabling market forces to supplement regulatory actions in motivating the shift to safer chemicals (Fisher, 2008). By requiring equivalent assessments of both old and new chemicals, the difference in cost between developing new (and potentially less hazardous) approaches and continuing the status quo is diminished. Furthermore, wide distribution of environmental hazard information allows the marketplace of hazardous chemicals to function more efficiently. However, the privatization of risk assessment also introduces problems concerning the legitimacy and quality of the resulting data, particularly if confidential business information is involved (Tietenberg, 1998; Stanton, 2005).

Some observers claim that the lofty goals of the movement that first conceived REACH were compromised through political means, leading to an "incremental" rather than "paradigmatic" change to chemicals policy (Pesendorfer, 2006). REACH is not geared towards

promoting preventive or precautionary action (Hansen et al., 2007); rather, the precautionary principle is situated within the broader hegemonic framework of risk assessment and risk management (Applegate, 2008). An example is provided by Annex XIV, the list of substances of very high concern. Annex XIV chemicals are the only substances for which REACH specifically identifies a mechanism to phase out; but the risks associated with a substance must be very thoroughly demonstrated before it can be added to Annex XIV. Final decision-making authority rests with the European Commission, a political agency. The time line for adding a chemical to Annex XIV is many years. Finally, substances are added one at a time, after exhaustive characterization and risk analysis. In this respect, REACH bears many similarities to TSCA. Since enactment of REACH in June 2007, only a handful chemicals or chemical classes have been identified as candidates for inclusion in Annex XIV, and that the total count of chemicals actually included stands at zero. These facts demonstrate that Annex XIV may represent a sluggish route to hazard reduction. However, given the long timeline for full adoption of REACH, this route may become more robust as implementation progresses.

Additionally, many chemicals produced in small volumes are completely excluded from regulation, and for many others (those produced quantities of less than 10 tons per year by any given company) no chemical safety or risk management data is required. Finally, the risk management requirements that do exist for larger-volume chemicals are based only on "identified uses," meaning that occasions for potential adverse effects that may exist and may even be easily foreseeable are not addressed (Santillo, 1999).

Alternatives assessment finds limited application in REACH. Again, there are provisions for widely distributed alternatives assessment to be performed once the Authorization rules of Annex XIV take effect; for now, however, the focus remains on quantitative risk assessment and risk management. Hazard reduction strategies which pursue precautionary or preventive approaches, such as alternatives assessment, in tandem with risk management approaches may be more effective than risk management alone (Koch and Ashford, 2006).

Chapter 3

Frameworks for Alternatives Assessment

The methodology for conducting Chemical Alternatives Analysis (CAA) is under ongoing development. At its core is a process for studying a product system and various options for changing it, known as "Alternatives Assessment." The first significant effort to formalize the process for alternatives assessment came from the US EPA in the mid 1990s as part of their "Design for Environment" program. Their "Cleaner Technologies Substitutes Assessment," (CTSA) published in 1996, was the first formal Chemical Alternatives Assessment framework. The modern era of alternatives assessment was marked by the publication of "Making Better Environmental Decisions" (O'Brien, 2000), which critiqued the risk-based paradigm for assessing chemical safety and presented alternatives assessment as a cheaper, more precautionary and more effective approach.

Since that time, a number of chemical authorities, businesses, and NGOs have developed strategies for combining alternatives assessment with existing evaluative frameworks for chemicals. However, few of those documents rise to the level of a formal methodology, and no contemporary effort has matched the EPA's CTSA in comprehensiveness. Modern chemical alternatives analysis frameworks, such as the Lowell Center's "Alternatives Assessment Framework" (Lowell 2006) and the Swedish Chemicals Agency's report on "The Substitution Principle" (KEMI 2007), share several common elements (see also Eliason and Morose, 2010):

- Use of qualitative and quantitative information

A fundamental part of alternatives-based approaches is in the recognition that a hazard exists. Understanding the potential consequences of the hazard can take both quantitative data (e.g. risks, costs) and qualitative information (e.g. existence or degree of health effects, assessments of ecosystem quality or ecological threats). Any decision-making framework for analyzing alternatives must be capable of integrating both forms of information.

- A diminished reliance on the results of risk assessment

Risk data provide a scientific basis for decision making by positively demonstrating toxicity or demonstrating the absence of observed effects. However, risk assessment is judged less reliable for demonstrating the absence of toxicity, and is also costly and can be highly uncertain. Alternatives-based approaches emphasize the incorporation of other metrics to supplement risk data.

- A description of the functional use of a chemical as a basis for developing alternatives

Chemicals are used because they perform useful functions in the manufacture or use of a consumer product. In order to find alternatives, it is necessary to understand clearly the role of the chemical of concern in achieving the product's function. "Alternatives" can be any changes in design, process, or management which accomplish essentially the same function.

- An iterative process of continuous improvement

Our knowledge of chemical hazards is uncertain and developing rapidly. At the same time, chemical use occurs in the context of established product systems and supply chains. Therefore, organizations should also endeavor to choose "safer" approaches whenever possible and make a long-term commitment to toxics use reduction.

It is also common for alternatives assessments to be highly case-specific, emphasizing a modular analytic structure. Analysts performing a CAA involving consumer products or high-profile chemicals should endeavor to involve a diverse array of stakeholders from industry and the public (National Research Council, 1996; Sinclair et al., 2007).

This chapter reviews major frameworks for chemical alternatives assessment, including CTSA, the Lowell Framework, and the emerging Green Product Innovation Institute in California. The chapter concludes with a discussion of life cycle assessment (LCA), a widespread methodology for estimating the environmental impacts of goods and services. Selecting a preferred course of action from among the considered alternatives is a complex process which is not included in many alternatives assessment frameworks. We address the topic of choosing among alternatives in Chapter 5 of this report.

3.1 EPA – Cleaner Technologies Substitutes Assessment

http://www.epa.gov/dfe/pubs/tools/ctsa/index.htm

The EPA made an early attempt to formalize alternatives assessment with its 1995 publication entitled "Cleaner Technologies Substitutes Assessment (CTSA): A methodology and resource guide" (Kincaid et al., 1996). This guidance document was issued as part of the EPA's Design for Environment (DfE) program. It was designed to assist industry partners in evaluating the "comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used" by the industry.

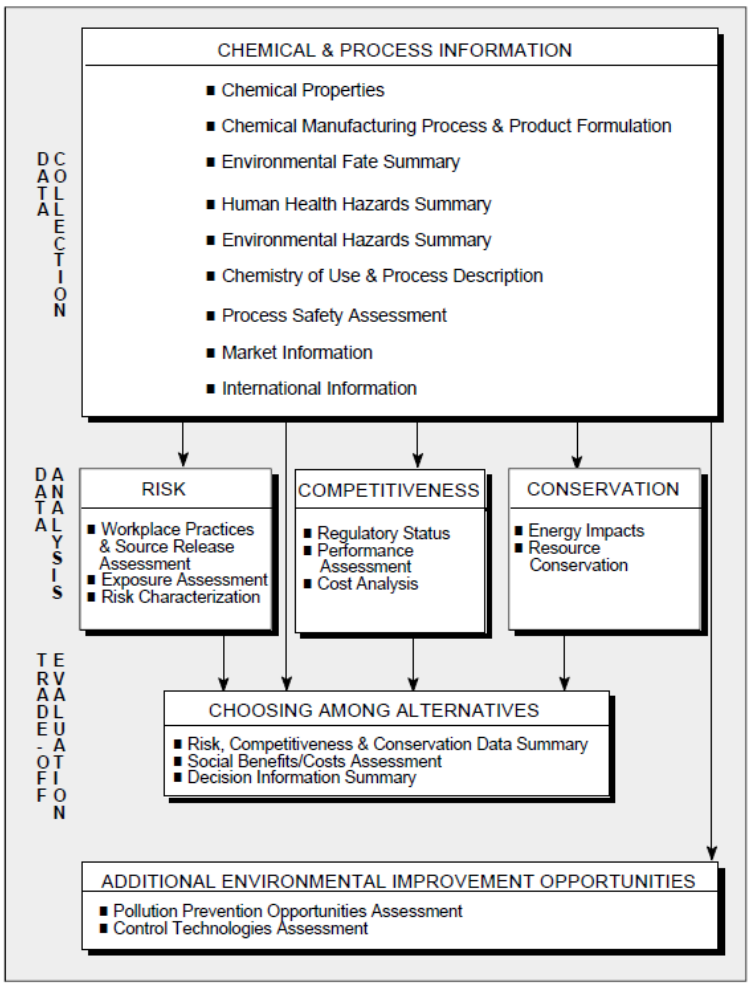
The approach outlined for CTSA involves the identification of "use clusters," which are essentially technical processes that can be performed in a number of ways. The use cluster is identified by the analyst as the focus area of the study. It is intended to correspond to an actual process currently in use. The methodology calls for finding processes that can essentially substitute for one another within a use cluster, and then comparing the processes against one another to determine superior alternatives. Definition of the use cluster in a CTSA is akin to definition of the functional unit in a life-cycle assessment (see section 3.5), except it is applied to a manufacturing process rather than a product system. The scope of use-cluster-based analysis is therefore somewhat limited, since it does not consider the end-use function of the product. Alternatives assessments based on use clusters will not necessarily include alternative technologies, product redesigns, or other ways to avoid the process altogether.

The CTSA methodology is designed to be modular, with different analysis components being suitable for different product systems or situations (Figure 3.1). However, unlike modern alternatives assessment approaches, the CTSA methodology is built on a foundation of risk assessment. According to the framework, the analyst is able to make an informed decision about substituting the process in question only after considering risk, cost, and performance together. Each point of evaluation (e.g. workplace practices, human health hazards, and so on) is represented by a module in the CTSA guidance document. The publication describes a total of 19 modules in the areas of chemical and process information, risk, competitiveness, conservation, and additional environmental improvement opportunities. Analysts may use all or only some of the modules, or create their own.

An innovation in the CTSA approach is the application of a standard structure to all modules. The format, described in Chapter 4 of the report, is oriented towards practitioners in industry. The module descriptions lay out the methodology for assessment in a step-by-step fashion. In addition, each module includes a set of goals, definition of key terms, and links to useful references and guidance. The module also describes its interdependence with other modules that may provide vital information. The standardized "recipe" approach gives the impression that CTSA is very easy to implement in an enterprise environment.

Once the modules are completed for each alternative, the alternatives are compared to one another. This step, entitled "choosing among alternatives," builds heavily on EPA's

Figure 3.1: The basic flow of information in a CTSA, showing different analysis modules (Kincaid et al., 1996).



expertise in risk management and is also modular. The three modules for comparison are the Risk, Competitiveness and Conservation Data Summary; Social Benefits/Cost Assessment; and Decision Information Summary. This stage is not designed to select an optimal alternative; rather it is intended to synthesize and present information about the relative benefits of the various alternatives. Completion of these final three modules in succession is intended to illustrate significant trade-offs, enabling the analyst to come to an informed decision. However, the modules do not specify how the comparison is to be made, nor do they address how such a wide array of information is to be presented in a meaningful way.

Application of the CTSA methodology is considered in two case studies in Section 6.2.2. Implementations of the methodology demonstrate that the modular approach is highly effective at collecting the pertinent information, but synthesis of data from all modules

into a usable decision support framework remained a weak area with room for improvement. The EPA eventually discontinued work on CTSA but continues to provide access to published materials related to the project.

3.2 Alternatives Assessment at TURI

The University of Massachusetts at Lowell, where the Toxics Use Reduction Institute is headquartered, has been at the forefront of alternatives assessment research since CTSA. In 2005 TURI published a white paper entitled "Alternatives Assessment for Toxics Use Reduction: a Survey of Methods and Tools" (Edwards et al., 2005). In this document the Institute and affiliated researchers establish the importance of alternatives assessment to pollution prevention, describe a variety of extant methods for assessing alternatives in toxic chemical use, and discuss implementation of these ideas in an industry setting.

The main focus of the document is on presenting a collection of techniques, developed by different agencies around the world, for comparing hazard characteristics of different chemicals. In all, the TURI framework identifies over 100 distinct tools which present and analyze environmental information, ranging from broad techniques like economic input-output LCA to consulting services provided by specific private firms. These techniques fall into two broad categories: "hazard data display methods" and "screening/decision methods." Hazard data display methods provide a structured way to compare the attributes of various substances against one another. Users are expected to produce their own rules for incorporating the data into the decision making process. Screening/decision methods contain built-in (and sometimes hidden) decision rules and can be used to identify chemicals with high risk or hazard. Here the results are contingent upon the assumptions made by the creators of the tool.

The document pares its focus to nine tools, comprising four hazard data display methods and five screening/decision methods, which it reports on in some depth. Regarding selection of the best alternative from a range of choices, the TURI document is less clear. It describes a number of techniques, including dominance analysis, positional analysis, and weighted-sum aggregation, which are taken from the field of multi-criteria decision analysis (MCDA, reviewed in section 5.3 below). However, it offers little more than broad recommendations for specific decision making.

The paper makes the case that alternatives assessment is a subjective process from which clear, analytic answers are not forthcoming. It also demonstrates that alternatives assessment can draw from an almost unbounded array of tools to gather and compare information. However, it does not provide guidance on how to make decisions following an alternatives assessment, or even on how to select among the tools it presents. Later work by the Lowell Center for Sustainable Production expanded on the work of this document

and is discussed in the next section. In 2006 TURI produced a landmark alternatives assessment for the Massachusetts legislature, which we review in Section 6.2.1.

3.2.1 The Lowell Framework for Alternatives Assessment

The Lowell Center for Sustainable Production distilled the TURI model into its own framework for Alternatives Assessment (Rossi et al., 2006). The Lowell framework document is among the most focused methodology documents on alternatives assessment available. The stated purpose of the document was to "[create] an open source framework for the relatively quick assessment of safer and more socially just alternatives to chemicals, materials, and products of concern." The framework document is brief (24 pages) and is meant as an informal guide to policymakers and practitioners who wish to implement alternatives assessment for toxic chemicals. The framework contains three "core elements": (i) a foundation comprising guiding principles, measurable goals and decision making rules; (ii) a procedure for developing a list of alternatives; and (iii) a collection of modules for evaluating the alternatives. The second and third elements are processes to be performed sequentially and iteratively. The defining features of the framework are its modular nature, enabling it to be extended easily, and its orientation around product end-use function.

According to the framework, manufacturers should aim to prevent the use of hazardous substances whenever possible by either substitution or product redesign, and should take whatever precautions are necessary to reduce threats to health and the environment. Renewable energy and feedstocks should be used whenever possible. Decisions should be made considering the full life cycle of the products and with input from many stakeholders. To enhance broad democratic participation, the process should be transparent and "open source" and subject to continuous improvement. Chemicals lacking safety data should be treated as hazardous, and every effort should be made to encourage stakeholders to develop quantitative results when possible. In the meantime, a lack of quantitative information should not be used as a justification for inaction if there is reasonable cause for health concerns. The search for alternatives to toxic chemicals should be broad, creative, and ongoing. This summary is not exhaustive and the original document should be consulted for more information.

The framework delineates a procedure for performing alternatives assessment subject to the principles above. Once a target chemical for action has been identified, the next step is to characterize and prioritize end uses which require use of the target. Analysts should develop a set of alternative processes, including chemical substitutions, process changes, and product redesign. The search for alternatives is likely the most significant step in determining the outcome of the process. The document recommends "a broad market survey and literature review as well as interviews with appropriate experts who have a broad perspective." No alternatives should be eliminated prematurely because of cost or feasibility concerns; rather, they should be evaluated for both present and future viability.

The evaluation of alternatives is the most intensive step in the process. The framework recommends an open-ended, modular approach in which multiple aspects of the alternatives are considered independently of one another. This is the key property of the framework, as it allows virtually any basis for comparison to be included in the analysis, and allows for sharing of methods between organizations. It is in the collection of evaluation models that the Lowell framework strongly emphasizes the "open-source" nature of its approach.

The framework lists a variety of different evaluation modules, but specifies that the list should be considered open-ended and extensible, and encourages stakeholders to develop new modules. The list of modules includes representatives from four categories: Human health and the environment; social justice; technical performance; economic feasibility. Each category includes a variety of existing tools produced by other agencies.

3.2.2 Options in State Chemicals Policy Reform

In 2008 the Lowell Center published a report discussing the role of state regulators in setting safer chemicals policy (Lowell Center for Sustainable Production, 2008). Building on work from California's Green Chemistry Initiative, the report focuses on ways states can create policies that help to address three central failures of extant chemicals regulations: the "data gap," "safety gap," and "technology gap" (see Wilson et al. (2006)). The report advises on seven different modules pertaining to chemicals regulation, including generating information, sharing knowledge, prioritization of hazardous chemicals, alternatives assessment, promoting green chemistry innovation, implementation, and emerging technologies. The report concludes that, while challenges are significant, there is great opportunity for states to take regulatory action to fill acknowledged gaps in federal laws.

The report's module on Alternatives Assessment recommends a seven-step plan that parallels the strategy presented in Lowell's 2006 Alternatives Assessment Framework document:

1. Identify all the chemicals used in the manufacture of the product, including the material chemistry of the product;
2. Evaluate the hazards of those chemicals;
3. Classify the chemicals into levels of concern (for example, high, moderate, or low concern);
4. Identify alternatives to chemicals of high concern;
5. Work with suppliers to provide preferred alternatives;
6. Evaluate, compare, and prioritize alternatives;

7. Select preferred alternative or substitution.

The module details a number of different strategies state governments can undertake to promote one or more of the above steps, noting that one or a few of them in isolation are unlikely to effect change. The module places emphasis on mandatory programs, such as reporting requirements, fees, and substance restrictions; incentive programs, such as tax credits; and technical assistance programs, such as those offered by the Massachusetts Office of Technical Assistance (see Section 2.3.3 above).

On the subject of selecting a safer alternative from a number of options, the module notes that a smaller scope of inquiry (for example, considering only a few hazard characteristics) may simplify decision making, while considering a large number of potential risks and hazards may "paralyze" the alternatives selection process. It observes that the definition of "safer alternative" is a crucial component in determining the result of the alternatives assessment, and recommends a flexible, dynamic process for analyzing alternatives. Ideally, alternatives assessment should be a process of "continuous improvement" and ongoing data collection. Providing incentives for businesses to engage fully with this challenge is an integral component of success. Alternatives assessment must be tied to a broader set of policy options in order to be effective.

3.3 Swedish Chemicals Agency (KEMI)

Sweden has long been at the forefront of chemicals policy reform. As early as 1969 the Swedish parliament adopted regulations that required chemical industry participants to demonstrate the safety of environmentally hazardous activities (Lofstedt, 2003). In 1990 the law governing industry's obligations to minimize harm to the environment was amended to include the substitution principle, which requires industrial actors to transition to safer alternatives if they are available (Wahlstrom, 1999).

However, the definition of "safer alternative" is not clear. This is by design. The Swedish Chemicals Agency (KEMI) defines the "substitution principle" thus:

> If risks to the environment and human health and safety can be reduced by replacing a chemical substance or product either by another substance or by some non-chemical technology, then this replacement should take place. All decisions on such substitutions should be based on the best available evidence. This evidence can be sufficient to warrant a substitution even if quantitative risk estimates cannot be made. (Swedish Chemicals Agency (KEMI), 2007).

In particular, the substitution principle should not be limited to replacement of one chemical with another, but may include reduction of the volume of hazardous chemicals used as well as transitioning from processes that require hazardous chemicals to processes that do not. The substitution need not have equivalent functionality to the original, because there are some situations in which threats to health or the environment outweigh the functional performance of chemicals. Finally, deliberations regarding substitution should take into account hazards (qualitative dangers) as well as risks (quantified dangers). The market is recognized to be an inadequate driver of substitution, and the agency concludes that "for the substitution principle to be efficiently implemented, regulators and public authorities have to take the lead." (Swedish Chemicals Agency (KEMI), 2007, 40).

According to the agency, the substitution principle leads to a chemicals policy which falls somewhere between the business-as-usual scenario of risk assessment and risk management, and a wholesale endorsement of the precautionary principle. Regulators should pursue a strategy of "science-based precaution" in which scientific data is used to inform a decision that is reflective of "cautious thinking" and risk aversion. Risk-based models must be supplemented with a consideration of potential uncertainties in or omissions from the risk model itself. And in the absence of hazard data, models should make risk-neutral assumptions (i.e. assume the substance has "average risk") rather than zero-risk assumptions (i.e. assume the substance presents no risk).

Implementation of the substitution principle is challenging, not least because of the lack of data about risks and hazards of many chemicals. The agency describes eight methods to encourage substitution of hazardous chemicals:

1. Increase the availability of toxicity data. The agency looks to REACH to fill this need (see below).
2. Increase the available data on the chemical composition of products. This goal is at odds with industry claims of confidentiality or trade secrets.
3. Increase the available information on technical functionality. In essence, this method describes a need for technical evaluation of alternatives which can be useful for industrial actors looking to apply the substitution principle in their operations.
4. Provide helpdesk functions. The agency cites the office of technical assistance developed in Massachusetts for TURA (see above).
5. Create Lists of unwanted substances. These can inspire companies that use the unwanted substances to embark on voluntary phase-out operations. KEMI developed PRIO, an online database of hazardous substances, to facilitate the assessment of health and environmental risks (reviewed in section 4.4.3).
6. Ban dangerous substances. The agency recommends that bans be used with great discretion, recognizing that alternatives must be available before a ban can be effective.

7. Required substitution plans. The agency again cites TURA.
8. Create economic incentives. The agency recommends taxes on problematic substances for which alternatives are available.

The agency does not appear to discuss a methodology for assessing possible alternatives or for deciding whether an alternative is "safer."

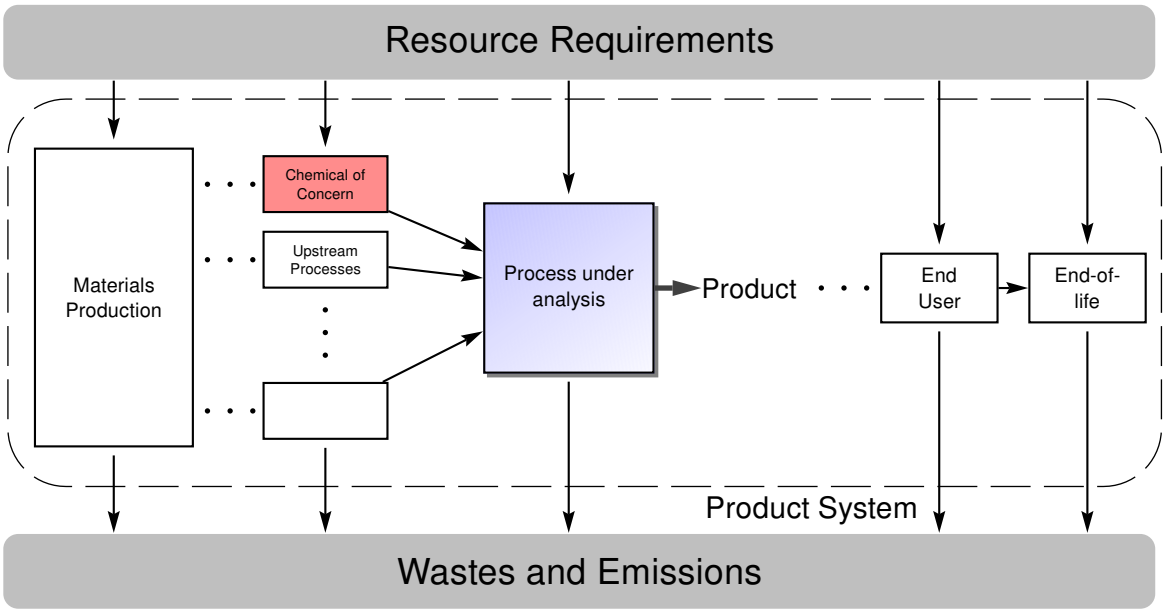
3.4 California – Green Products Innovation Institute

In December 2009 a consortium of business leaders, public officials and individuals founded the Green Products Innovation Institute, a non-profit organization based in California with the goal of providing training and certification to manufacturers of products that are "safe for the environment." GPII is intended to be an open, collaborative effort that both improves the quality of products available for sale in California and advances international research in developing safer alternatives to chemicals of concern (Anonymous, 2010). The certification program used by the institute is based on the Cradle to Cradle (C2C) design protocol developed by the consulting firm McDonough Braungart Design Chemistry. Previously proprietary, the C2C certification process will now be publicly available and will be maintained and administered by the GPII. The Institute plans to perform its own certifications as well as train licensed third party assessors to evaluate products. To date, the Institute has not yet begun normal operations. For more information on the C2C design protocol, please see section 5.5.1.

3.5 Life Cycle Assessment

Modern consumer products are commonly the result of a long and complex chain of industrial processes. They are often produced from raw materials extracted from the earth and refined into commodities such as steel or ethylene. Different refined materials are brought together in a series of manufacturing processes to create products which can be sold to consumers. Between successive manufacturing stages, materials or components may need to be packaged and shipped from one facility to another, sometimes crossing international borders. After the products are used they are either disposed or dispersed into the environment. Disposal may entail depositing the product in a landfill, recovering it for reuse or recycling, or incinerating it to produce energy. This network of processes taken together, from raw material extraction to final disposal, is called the product's "life cycle." At every stage of a product's life cycle, the processes involved are likely to have environmental impacts. For instance, manufacturing processes require the production of energy; intermediate packaging requires the consumption of packaging products and generates waste. Consumer use of chemical products may result in their dissipation into

Figure 3.2: A schematic drawing showing a fragment of a product life cycle, viewed in the context of a single process under analysis.



the environment or into municipal water treatment facilities. All along the way, fuels are required for transport.

Life cycle assessment (LCA) is a widespread methodology for evaluating the aggregated environmental impacts of goods and services Rebitzer et al. (2004); Hauschild (2005). Life cycle assessment is defined by an international standard published by the International Standards Organization (International Organization for Standardization, 2006). In essence, it consists of the documentation of the sequence of technological processes which must occur in order to bring a certain product or a certain service to a consumer of that product or service. It emphasizes measurable flows of physical substances, and its scope is the entirety of the product's life cycle, from the original extraction of materials from the earth to the final delivery of all wastes to points of disposal.

The product system is defined by the "functional unit," a quantitative statement of the utility or service the product provides to the consumer. All impacts of the product system are given in reference to this unit of service or performance. The resource requirements and impacts of different product systems which provide the same utility can then be compared on equal footing. The core of an ISO-style LCA is the network of "unit processes" necessary to produce and deliver the product to the consumer, which correspond to the industrial processes described above. The network of processes includes both direct manufacturing processes and supporting processes like energy generation and manufacture

of supplies.

An ISO-style LCA consists of four stages:

Goal and scope definition describes the product system under study, defines the functional unit, and develops the boundaries of the analysis, including which processes are included and which are exluded.

Life cycle inventory analysis describes the network of industrial processes in depth and characterizes their resource requirements and emissions into the environment.

Life cycle impact assessment assigns environmental impacts to the resource requirements and emissions developed in the previous stage, and aggregates them together to measure the cumulative environmental impact of the product system (see Section 4.3).

Interpretation of the results of inventory and impact assessment in order to identify the most impactful processes or aspects of the product system and generate opportunities for improvement.

Like other forms of product assessment, LCA is designed to be iterative. Preliminary LCAs which include rough estimates of resource usage can be refined with direct data collection. System boundaries should also be revisited throughout the assessment to determine whether processes with significant impacts are being omitted.

When approached from the perspective of a single production stage or manufacturing process, it may make sense to consider a fragment of a product system's life cycle as an initial screening tool (see Figure 3.2). Evaluating a fragment of a product system can be helpful when certain processes are unknown to or poorly understood by the life cycle analyst. In the context of LCA, a fragmentary analysis is of little value since it is impossible to know what has been left out. However, for CAA considering a fragment of a product life cycle can lay important groundwork for developing and evaluating alternatives even if their full life cycle impacts are not represented. At minimum, a life cycle fragment should include a specific process under study, the immediate upstream and downstream processes, the products end of life, and an approximate accounting of the raw materials that are used to make the product.

An LCA is an intensive, quantitative analysis of a product system. LCA is increasingly used by businesses, academic researchers and government agencies to understand the environmental implications of industrial activities. Comparative LCAs, in which two alternative product systems are compared, can also be performed. Because LCA is standardized and widespread, it is an ideal tool for measuring the environmental impacts of products and for comparing alternative processes or strategies. The use of a network of industrial processes as a modeling tool provides a foundation for relating the assessment to the existing industrial system. However, an LCA can be costly and time-consuming to

prepare. Its reliance on quantitative data can be burdensome, and there are wide gaps in data availability. Efforts are ongoing to develop databases of "life cycle inventories" which describe common industrial processes, but LCA of a specific product system will probably require some direct measurement of resource use and environmental emissions. Companies which apply life cycle thinking in their process management, and which undertake life cycle assessments of their products, will have a greater understanding of their "environmental footprint" than companies which do not.

Chapter 4

Tools and Resources

A core element of CAA is the identification of both the potential threats caused by the chemical of concern and the potential benefits and drawbacks of alternative solutions. An important aspect of this comparison is knowledge of the intrinsic properties of the chemicals themselves—whether they interact badly with living organisms or persist in the environment. Tremendous effort has been invested to understand the properties of chemical substances and some are very well characterized. The harmful properties of chemicals are examined directly through empirical animal or plant studies. However, for the majority of chemicals there is little or no empirical information on their effects (Wilson et al., 2006). Instead, toxicologists increasingly rely on a form of computational modeling known as structure-activity relationships (SAR, also QSAR for Quantitative SAR) in which chemicals are evaluated based on their structural similarity to substances which have been characterized. These screening tools can be used to identify potential chemicals of concern for further study.

This chapter covers an assortment of freely available tools for characterizing the properties and known hazards of chemical substances. We review single-substance databases and meta-databases and briefly discuss a suite of screening tools maintained by the US EPA. The rise of life cycle assessment for evaluating the environmental performance of products has led to a need for integrative data tools which describe the relative impacts of different chemicals when they are emitted into the environment. We describe these life cycle impact assessment characterization data sets in the third section. Finally, three integrated tools for evaluating substances are discussed.

4.1 Substance Information Databases

4.1.1 European Substances Information System Database (ESIS)

http://ecb.jrc.ec.europa.eu/esis/

This web-based meta-database is intended to be a complete reference for accumulated information on the potential hazards associated with chemicals. It aggregates data from a number of other European databases, including the European Inventory of Existing Commercial chemical Substances (EINECS), persistent, bio-accumulative, and toxic chemicals (PBT and vPvB), risk assessment reports submitted to the European commission, as well as other lists and registries that are significant to the European chemical regulatory regime. It is cross-referenced and fully searchable by substance name or CAS number. Use of this resource is highly recommended for practitioners wishing to quickly find information regarding the potential hazards of chemical substances.

The main search window provides a portal to all included information, and so this database functions as a "one-stop shop" for hazard information. The database gives a list of labeling terms associated with each chemical, including risk phrases and safety phrases. The CAS number provides a universal key on which to stage a search, since each substance has a unique CAS number which is uniform and consistent around the world. Searches based on substance names can be unreliable (for example, 'perchloroethylene' is not in the database, but its synonym 'tetrachloroethylene' is included. The database provides access to a 185-page data sheet about this chemical). The CAS number is highly recommended as a search key. At the time of writing, the EINECS database included over 100,000 substances, although substantially fewer of these are accompanied by chemical data.

The chemical data sheets supplied by ESIS are basically organized lists of all available data about the chemical. Each data entry comprises a data point and a source, along with remarks made by the source when contributing the data. Data sources tend to be companies or government agencies which have performed tests on the chemical, but also include references to published literature. For instance, the data set for acenaphthene includes five different measurements of its melting point, taken from two textbooks, two research papers and one internal study, spanning a period of 24 years. The figures fall within a range of 4.2°C. All five figures were reported by a single company. Looking at the listing of data gives a very good impression of the history of information about the substance. The reports are substantial and highly informative when they are available, particularly when considering well-studied chemicals. However, for many chemicals in the database no hazard information is available. ESIS also provides access to the results of risk assessments, when they are available.

The ESIS database appears to be extremely useful to both respondents and regulators for obtaining information about chemical hazards. The fact that it is in heavy use within the EU for chemicals regulation suggests that the data will be of highest available quality and the database contents will be continuously improved. However, it is not clear how often the data sheets are updated. Use of the database appears to be the quickest way for users to access the data collected to meet EU-REACH requirements.

4.1.2 Aggregated Computational Toxicology Resource – ACToR

http://actor.epa.gov/actor/faces/ACToRHome.jsp

ACToR is EPA's new meta-database of chemical information. First opened to the public in 2008, ACToR aggregates over 500 public data sources and currently has knowledge of over 540,000 unique or generic chemicals (US Environmental Protection Agency, 2010). It is designed to present a comprehensive view of what is known about any given chemical. In a search result, each individual data source indexed by ACToR is linked for follow-up research. ACToR's designers mean for the database to include "essentially all publicly available information on chemical identity, structure, physical-chemical properties, *in vitro* assay results, and *in vivo* toxicology data" (Judson et al., 2009). Among the databases accessed are ToxRefDB, a newly created comprehensive index of *in vivo* animal tests, and DSSTox, a database of structure-activity relationships. ACToR also indexes established EPA programs such as the High Production Volume (HPV) challenge program and the Toxics Release Inventory (see section 4.1.6.

ACToR organizes its data according to the data structure model used by PubChem, a project of the National Library of Medicine. The format distinguishes between substances, compounds, and bioassays. A bioassay data object contains the results of a particular test run using a specific substance. The substance is one sample of a compound, which is associated with a particular chemical structure. To this framework, ACToR adds a generic chemical, which aggregates a compound with all the substances which reference it (Judson et al., 2008). EPA has used ACToR to screen and characterize 9,912 "environmental chemicals" being considered for regulation in order to select candidates for in-depth analysis (Judson 2009). ACToR is under active development and is implemented using open-source software in order to facilitate its growth and adoption by organizations outside the EPA (Judson et al., 2008).

4.1.3 National Institute of Health – Toxnet

http://toxnet.nlm.nih.gov/index.html

The Toxnet meta-database is an online tool for searching across 14 other chemical databases. Several of these are also maintained by the NIH through the National Library of Medicine. These include:

TOXLINE, toxicology literature search;
ChemIDPlus, basic chemical information;
HSDB, Hazardous Substances Data Bank;
CCRIS, Chemical Carcinogenesis Research Information System;

DART, Developmental And Reproductive Toxicology information center;
LactMed, information on chemicals and breastfeeding;
Haz-Map, information on occupational exposure to chemicals;
the Household Products Database;
TOXMAP, a geographic representation of TRI data.

Other databases maintained by outside groups are also included in Toxnet. These comprise:

GENE-TOX, information on mutagenic chemicals (EPA);
IRIS, Integrated Risk Information System (EPA, see below);
ITER, toxicology estimates (Toxicology Excellence for Risk Assessment);
TRI, the Toxic Release Inventory of industrial chemical emissions (EPA);
CPDB, Carcinogenic Potency Database (University of California and Lawrence Berkeley Lab).

Searching by keyword, chemical name, CAS number, or any other search term will return a count of the number of times that term occurs in each database, along with a link to access the references.

The most useful data from the Toxnet service comes from NIH's own Hazardous Substances Data Bank (HSDB), which features the results of peer-reviewed studies on human, animal, and environmental effects, laboratory methods, occupational and safety practices and standards, and other information. Toxnet also provides access to a number of other toxicology-related resources maintained by the NIH and other public agencies.

Toxnet is actively maintained and frequently updated. Its simple interface provides very quick access to a wealth of public sources.

4.1.4 eChem Portal

http://webnet3.oecd.org/echemportal/Home.aspx

eChem Portal is an effort of the OECD, in collaboration with the European Commission, the United States, and several other nations and international business groups, to develop an internationally standardized source for chemical hazard information. The eChem Portal provides aggregated search results for 17 international databases and meta-databases, including ACToR and ESIS. Upon a successful search, the portal provides links to positive results in any of the participating databases. Data are not further reviewed or processed by the portal itself, and the user is directed to the participating databases for follow-up information.

4.1.5 EPA Substance Registry Service

http://iaspub.epa.gov/sor_internet/registry/substreg/home/overview/home.do

The EPA Substance Registry Service is the EPA's main database for information about regulated substances. Like ESIS, the service is essentially a meta-database, including substances that are tracked by different programs within the EPA. Searching for a chemical by name or CAS number will produce a list of lists which include the substance, as well as a list of synonyms for the substance. Finally, documents which make reference to the substance are reported and made available to the user. The service provides access to the EPA Ecotox database and the EPA IRIS database, both of which are discussed separately below. Other databases, such as that maintained by the National Institute for Occupational Safety and Health, are also included but are not discussed here.

Depending on the substance, a significant amount of information is available, ranging from laboratory studies to medical reports. However, it is slightly more cumbersome to locate and collect the information which is available. Because the Substance Registry Service is oriented around existing chemical regulations, the documents it returns tend to be relevant to regulatory affairs.

4.1.6 EPA Toxics Release Inventory (TRI)

http://www.epa.gov/tri/

The Toxics Release Inventory is a public, searchable database of environmental releases of over 500 toxic chemicals by industrial facilities. The TRI was created in 1986 by the Emergency Preparedness and Community Right to Know Act (EPCRA; see section 2.2.2). The EPA maintains a list of chemicals and any facility which uses any chemical on the list in excess of 10,000 lbs per year, or manufactures a chemical in excess of 25,000 lbs per year, is required to report its environmental emissions to the database. Using the TRI tool, members of the public can obtain information about environmental releases of given substances or from specific facilities. All environmental releases are self-reported.

A strength of the TRI program is its incorporation into a variety of data visualization tools that enable ordinary citizens without a sophisticated understanding of toxicology to inspect the contents of the TRI database. The TRI Explorer (http://www.epa.gov/triexplorer/) provides quick access to a list of facilities near a ZIP code, by state or county, or by chemical reported or reporting industry. The TRI has also developed a framework called TRI.net (http://www.epa.gov/tri/tridotnet/) which is intended to facilitate the development of outside tools for data access and visualization. One example of such a tool is the "TRI to Earth" tool which integrates TRI data with Google Earth

(http://www.turboperl.com/google/), a popular online global atlas. These tools expand access of public information to a wider range of stakeholders, contributing to the goals of the EPCRA legislation.

4.1.7 EPA IRIS

http://www.epa.gov/iris/index.html

IRIS is the EPA's Integrated Risk Information System, and it serves as a clearinghouse for risk assessment data. At the time of writing, IRIS included 553 substances. Supporting documentation is also supplied for the most recently added chemicals in the form of a toxicological review. 67 chemicals feature this supporting data.

Search is by name, CAS number, or keyword, although because of chemical naming ambiguity, the CAS number is the preferred method. It is also possible to view a full listing of all substances in the database, sorted by name, effect, toxicity, carcinogenicity, or by the level of uncertainty. The data supplied include estimates of the reference dose for chronic oral exposure, reference concentration for chronic inhalation, and carcinogenicity assessment. Synonyms and bibliographic information are also supplied.

4.1.8 EPA ECOTOX

Database: http://cfpub.epa.gov/ecotox/

Code List: http://cfpub.epa.gov/ecotox/blackbox/help/codelist.pdf

ECOTOX is the EPA's database of empirical data on the toxicity of chemical substances to aquatic and terrestrial organisms subjected to controlled exposure to toxic substances. The ECOTOX database contains the results of published laboratory tests, stored in an abstract format, meaning that various significant parameters of the published reports are represented by codes in the ECOTOX database. Deciphering the code requires reference to a code list, which is published along with the database. Other information about the test, including the experiment type and duration, concentration of the chemical, location of the test in the lab or in the field, and other items, is also provided. Because the test records are stored in an abstract format, it is important to review the actual studies on which the records are based in order to understand how to interpret the results.

ECOTOX is maintained by the Mid-Continent Ecology Division of the EPA. The ECOTOX maintainers endeavor to incorporate all applicable published literature into the database. As of December 2009, the database included information on 9,180 chemicals and appears to be updated frequently. Searching by chemical name or CAS number will produce a list

of test records for the chemical, sorted by the species tested. Each record is accompanied with bibliographic information.

ECOTOX is a highly specialized tool. Though the database provides abundant quantitative information, it is necessary to be familiar with live-animal testing methods and techniques in order to decipher the meaning of the data. The information in the database should be used with great care in order to ensure that the data are interpreted correctly.

4.1.9 Scorecard Chemical Profiles

http://scorecard.org/chemical-profiles/

Scorecard was originally developed in 1998 by the Environmental Defense Fund to provide information about pollution to the public. In 2005 they transferred maintenance of Scorecard to Green Media Toolshed, a nonprofit organization dedicated to "strengthening the communications infrastructure for the environmental movement." Scorecard provides a searchable database of information about health and environmental hazards associated with chemicals. The database can be searched by substance name or CAS number. Scorecard also includes a portal to Toxics Release Inventory (TRI) information, information on federal environmental regulation compliance organized by locality, and other information. Scorecard does not appear to produce any of its own data; instead, it aggregates information publicly available from governmental sources, mostly in the EPA.

For a given chemical, the Scorecard chemical profile provides a list of known information about human health hazards, chemical use, regulatory coverage, and safety information which is lacking or unavailable or testing which has not yet been performed. For well-studied chemicals, Scorecard provides access to a fairly complete record of hazard information. Chemicals not under regulatory coverage have almost no information available in Scorecard.

Scorecard provides a useful aggregation of public data about chemical substances, and can be considered a first step to compiling a dossier of hazard information. However, Scorecard contains no information that is not generally available from other sources. Furthermore, Scorecard's private ownership suggests that its future accessibility and accuracy may not be reliable. The Massachusetts TURAData web portal references Scorecard for chemical hazard information.

4.2 EPA Screening Tools

Screening tools are designed with the intent of filtering a large list of potentially hazardous chemicals into basic categories, quickly identifying chemicals that are clearly hazardous

and selecting a subset of chemicals for in-depth study. They are most useful in situations when too many alternatives exist for a full alternatives assessment. Screening tools make use of limited information and rapid data entry to facilitate consideration of a large number of substances. They tend to take make conservative assumptions about potential adverse effects, meaning they are designed to produce more false positives (safe chemical identified as dangerous) than false negatives (dangerous chemical identified as safe). Screening tools should not be used for chemicals for which experimental data are available.

The screening tools published by the EPA can be loosely grouped into exposure-estimation methods and hazard-estimation methods. Exposure-estimation methods are designed to predict the level of exposure that may result from a chemical's intended use or expected release. Because of differences in chemical properties, some chemicals are more likely to result in hazards than others even when released in the same amounts. Hazard-estimation methods, on the other hand, are intended to estimate the hazardous properties of unknown substances. Hazard estimation methods tend to rely on results from quantitative structure-activity relationship analysis or Q-SAR.

For the most part, the tools can be downloaded and run on a personal computer running Microsoft Windows. A few of the tools are available online.

4.2.1 Exposure-screening Methods

http://www.epa.gov/oppt/exposure/index.htm

ChemSTEER or Chemical Screening Tool for Exposures and Environmental Releases, aims to estimate exposure to workers or the environment when chemicals are used in an expected fashion. It makes use of physical and chemical properties of substances as well as a database of functional information about end-use operations. (updated May 2004)
http://www.epa.gov/oppt/exposure/pubs/chemsteer.htm

E-FAST is designed to estimate likely levels of exposure that will result from routine chemical releases from facilities or products. It combines a number of special-purpose tools into a single program. Some of the tools have undergone peer review. (updated October 2007)
http://www.epa.gov/oppt/exposure/pubs/efast.htm

EpiSUITE is the product of collaboration between the EPA and Syracuse Research Corporation. It estimates exposure characteristics of a chemical, such as partition coefficients and reaction rate constants, based only on the chemical's atomic structure. EpiSUITE is a hybrid tool with both exposure- and hazard-estimation features. (updated January 2009)
http://www.epa.gov/oppt/exposure/pubs/episuite.htm

4.2.2 Hazard-estimation Methods

http://www.epa.gov/oppt/sf/tools/methods.htm

PBT Profiler, like EpiSUITE, uses the atomic structure to estimate properties of a substance, but focuses on properties relating to persistence, bio-accumulation, and toxicity. It estimates the rate at which the chemical will break down in various environments. Only the 'Persistence' component of the PBT profiler is unique; the 'B' and 'T' components are also available in EpiSUITE. PBT Profiler is an online tool available at http://www.pbtprofiler.net

ECOSAR is the toxicity subcomponent of EpiSUITE and PBT Profiler, also available as a stand-alone tool. ECOSAR, or Ecological Structure-Activity Relationship estimator, attempts to estimate the toxicity potential of a substance based on its atomic structure. (updated February 2009)
http://www.epa.gov/oppt/newchems/tools/21ecosar.htm

OncoLogic uses SAR to predict the carcinogenicity potential of chemicals. It functions as an "expert system," asking the user a series of questions about the chemical, interpreting the responses in terms of its built in knowledge model, and developing an estimate of carcinogenicity potential. (updated 2005).
http://www.epa.gov/oppt/newchems/tools/oncologic.htm

AIM, or Analog Identification Methodology, can be used when all else fails. It estimates toxicity hazard by comparing an unknown chemical to analogs which have been tested. AIM is an online-only tool. (updated September 2009)
http://www.epa.gov/oppt/sf/tools/aim.htm

4.3 Life Cycle Impact Assessment

Many of the tools mentioned above focus on characterizing individual chemicals with respect to a wide variety of potential hazards and risks. In contrast, life cycle assessment (see Section 3.5) is concerned with contributions from a wide variety of chemicals to specific categories of impact. In order to integrate the impacts of many different chemical substances, LCA practitioners and researchers have developed life cycle impact assessment (LCIA) tools which characterize the impacts of different chemicals relative to a reference substance.

Life cycle assessment is defined by an international standard published by the International Standards Organization (International Organization for Standardization, 2006). In essence, LCA consists of the documentation of the sequence of technological processes which must occur in order to bring a certain product or a certain service to a consumer. It emphasizes measurable flows of physical substances, and its scope is the entirety of the

product's life cycle, from the original extraction of materials from the earth to the final delivery of all wastes to points of disposal. An intermediate result of a life cycle assessment is called a life cycle inventory (LCI), which is a list of elementary material flows from the environment into the human technological/economic system and from human society into the environment. The purpose of life cycle impact assessment (LCIA) is to characterize those flows in terms of their impacts on the environment.

According to ISO 14044, LCA practitioners select a set of impact categories they wish to include in their analysis. Each impact category reflects a particular environmental concern and is described by a particular indicator. The indicator expresses a quantitative estimate of the the magnitude of the impact in that category. For every substance that contributes in a given impact category, a characterization model must be developed to describe the amount of its contribution. This factor is based on a scientific model of the chemical or material's behavior in the environment.

For example, global warming potential is a commonly considered impact category. Carbon dioxide is the primary contributor to global warming potential, so it is selected as the indicator for global warming potential. Substances which contribute to global warming potential are described in terms of "mass of carbon dioxide equivalent" the amount of carbon dioxide that would be required to create the equivalent global warming impact. Methane is another greenhouse gas which is about 25 times more potent than carbon dioxide in terms of global warming potential. In other words, one kilogram of methane isequal to around 25 kilograms of carbon dioxide, so methane's global warming characterization factor is 25. Substances can be implicated in multiple impact categories. For instance, methane can also be characterized in terms of its contribution to photochemical oxidation (smog) creation potential.

Often the time or location at which the emission occurred, as well as the nature of the release, are unknown or ambiguous, so impact characterization models are usually simplified forms of current scientific knowledge. Most models are steady-state and linear, taking the form of a constant number known as a characterization factor. In this case, the magnitude of a given chemical's flow times the characterization factor for that chemical equals the magnitude of the impact due to that chemical. The total impact in a given category equals the sum of impacts from all chemicals which have effects in that category. To the extent that LCIA produces a scientific measurement of the substances entering the environment as a consequence of a given activity, it is well-suited to be integrated with risk assessments and decision analysis (Christensen and Olsen, 2004; French and Geldermann, 2005; Shatkin, 2008).

Because the number of chemicals known is in the many thousands, preparing a complete set of characterization factors for even one impact category is an enormous task. LCA analysts usually rely on one or more published LCIA models which are prepared and maintained by LCIA specialists. Many LCIA models are available. Here we discuss two prominent contemporary efforts.

4.3.1 TRACI

http://www.epa.gov/nrmrl/std/sab/traci/

TRACI, or Tool for the Reduction and Assessment of Chemical and other environmental Impacts, was developed by the US EPA in the late 1990s and early 2000s (Bare 2003) and is available for free on the Agency's website. The most recent version available includes characterization factors that were released in 2002, but the agency is very close to releasing an updated data set (Bare, personal communication, 2009). TRACI includes characterization factors for 12 different impact categories, including carcinogenic and non-carcinogenic human health effects and eco-toxicity, as well as global warming, smog formation and others.

Although the current data set is fairly old compared to others available, TRACI remains the only impact assessment model specifically designed to represent US conditions, and remains popular for that reason. In addition, the release of updated data will make TRACI one of the most up-to-date impact assessment models. Because it is publicly available, it is an ideal resource for independent practitioners of US-based life cycle assessment to evaluate environmental impacts.

4.3.2 USEtox

http://www.usetox.org

USEtox is a collection of impact assessment models for toxicity and human health impacts meant to reflect scientific consensus on the best available impact assessment data. USEtox was developed by the United Nations Environment Programme (UNEP) and the Society for Environmental Toxicology and Chemistry (SETAC) under the joint UNEP-SETAC Life Cycle Initiative, begun in 2002 to disseminate life cycle assessment tools and resources (Hauschild et al., 2008). Life cycle researchers recognized a growing need to unify and harmonize the many disparate impact assessment models that developed during the early days of life cycle assessment. A process of "comparison and consensus" was put forth under which scientists representing the different models met in a series of work groups to fill data gaps and resolve discrepancies between prominent models.

The USEtox characterization factors were first published in 2008 (Rosenbaum et al., 2008). At the heart of the data set is a "consensus model" for health and toxicological impacts which includes only the most influential elements of other models. These elements were reviewed and harmonized with one another in order to be included in the consensus model. As a result, the range of discrepancy between different impact assessment methods was substantially decreased (from 13 orders of magnitude in some cases to a maximum of 2 orders of magnitude). However, the uncertainty that remains is still quite significant. USEtox includes recommended characterization factors for 991 organic substances

for human toxicity and 1,299 substances for freshwater eco-toxicity. The data set also includes 'interim' factors for an additional 260 substances (human) and 1,247 substances (freshwater).

USEtox developers are continuing to refine and broaden the consensus in an effort to further reduce uncertainty. The characterization factors discussed in the above paper (Rosenbaum et al., 2008), including interim values, are freely available online at http://www.usetox.org.

4.4 Integrated Tools

The following tools have been produced by government agencies or NGOs with the goal of simplifying the process of evaluating chemicals. These tools are each designed to evaluate a single substance at a time, though the results of evaluating different substances can be compared easily. The tools require data collection to be performed separately, and generally do not provide additional information about the substances in question. Instead, they standardize the evaluation of substances in ways that can be adapted easily for decision analysis techniques (see chapter 5).

4.4.1 Clean Production Action – Green Screen

http://www.cleanproduction.org/Green.Greenscreen.php

The Green Screen is a chemical evaluation tool produced by the nonprofit organization Clean Production Action. Guided by the principles of green chemistry and design for environment, the tool's designers set out to create a method for evaluating chemicals that was transparent (decision criteria are known to everyone), hazard-based and qualitative while taking a precautionary stance towards protection of human health and the environment (Rossi and Heine 2007). The result is a free, fully documented publicly available assessment system for ranking the level of intrinsic hazard presented by chemicals. The Green Screen comprises a set of four "benchmarks," each of which is defined by a set of decision rules involving a number of hazard categories. Benchmark 1, highest concern, indicates a chemical that should be avoided; Benchmark 4 is only achieved by "safer" chemicals, which are preferred. A chemical can only achieve a given benchmark by passing all of the associated decision rules.

The hazard categories include threats to human health, ecotoxicity, and environmental fate as well as physical / chemical properties. The criteria, which include both qualitative and quantitative thresholds, were chosen by expert judgment based on reviews of existing hazard classification schemes, including the Globally Harmonized System for chemical

labeling, assessments for the US EPA's Design for Environment program, and classifications from other state, national and international authorities in the US and abroad. In many cases, these classifications are quantitative values themselves based on empirical testing and risk analysis, but the Green Screen also includes "weight-of-evidence" criteria and other qualitative hazard assessments. Chemicals for which little or no empirical hazard data are available should be evaluated using structure-activity relationships (SAR) or other computational modeling. In all cases, the thresholds should be applied to the chemical in question as well as its degradation products and metabolites.

An important characteristic of the Green Screen is that the decision making process is qualitative, i.e. it does not involve the scoring of attributes or weighting of preferences by the decision maker. The outcome of using the tool is a table listing a chemical's level of concern (low, medium, high, very high) for each category of hazard assessment. The contents of this table can be used to determine what benchmark level the chemical receives. The Green Screen includes no mechanism for selecting among competing alternatives. The tool is under active development, with version 2 under peer review at the time of this writing, and remains free and open-source.

4.4.2 Germany – The Column Model; The Five Steps Matrix

http://www.dguv.de/bgia/en/pra/spalte/spaltmod.pdf
http://www.umweltdaten.de/publikationen/fpdf-l/2326.pdf

The Column model is essentially a ranking of established "risk phrases" ("R-phrases") which are used throughout the European Union to describe the documented hazards associated with chemicals. The column model consists of a table with six columns labeled, "Acute toxicity", "chronic toxicity", "environmental hazards", "fire and explosion hazards", "exposure potential", and "hazards caused by procedures". Within each column, assorted risk phrases and other criteria are listed in descending order from "very high" to "negligible" risks. Users are meant to use the criteria as a checklist for considering each substance under evaluation. Simply by inspecting the chemical's material safety data sheet (MSDS), the user can determine which risk phrases apply. The end result of the process is an array of rankings in each of the six categories. The rankings of chemical alternatives can be compared to determine if one is substantially less harmful than the other.

The column model is very easy to understand and fairly easy to apply, although the use of R-phrases may be unfamiliar to the American practitioner. Because R-phrases are not included on American MSDSs, it may be difficult to use the model. Users are advised to consult the European Substance Information System database, which is freely available online, to find R-phrase information by CAS number (see Section 4.1.1).

The Five Step matrix is an assessment protocol developed by Ökopol Institute for Environmental Strategies and Fraunhofer Institute for Systems and Innovation Research (Ahrens

et al., 2003). Based on the column model, the five step approach extends the principle of side-by-side comparison to include environmental aspects such as persistence, bio-accumulation, and toxicity. The methods document also describes how to add a category weighting to the columns in order to come up with a single quantitative score for each chemical.

The "five steps" are (p.18):

1. Taking inventory of chemicals with regard to use patterns and substance properties based on information at hand;
2. Stepwise elaboration of risk profiles;
3. Systematic evaluation of potential releases;
4. Characterization of hazardous properties;
5. Selection of an adequate management strategy and elaboration of safety measures.

These methods are useful as demonstrations of simple qualitative comparisons. In concert with the European substance database, which provides listings of risk phrases, these tools could function as a basis for quick comparison of the relative hazards of different substances.

However, the tools do not offer much more than a particular interpretation of relative severity, and application of the tools will provide little insight as to the sources of hazards or potential to reduce hazards. In summary, the documents may provide valuable reference material to regulators and respondents but do not contribute substantially to alternatives analysis.

4.4.3 Sweden – PRIO Tool for Risk Reduction of Chemicals

http://www.kemi.se/templates/PRIOEngframes____4144.aspx

The Swedish Chemicals Agency has produced PRIO, which is a web-based tool for assessing the risks to human health and the environment from chemicals. It is intended to function as both a priority-setting tool and an informational database. Chemicals are described in terms of two categories. "Phase-out substances" are of such high concern that they should not be used, and companies using these substances are required to transition to alternatives. "Priority risk-reduction substances" carry high risks but do not rise to the level of mandatory phase-out. All other chemicals are not included in the PRIO database. The main keyword for searching the database is the CAS number.

The web tool includes brief descriptions of the criteria used in identifying "phase-out" and "priority risk-reduction" substances. In short, the criteria come from risk phrases

or “r-phrases” where those are available, and ad-hoc criteria otherwise. In cases where standard r-phrases are not available, in-depth testing information is provided.

The tool is highly oriented around Swedish regulations and is mainly useful for US practitioners as a substance information database. However, in this capacity it is not as useful as the other dedicated resources discussed in Section 4.1.

Chapter 5

Choosing Among Alternatives

Chemical Alternatives Analysis (CAA) is intended to help organizations identify opportunities to reduce toxic hazards or reduce the risks associated with those hazards. Through the process of documenting the existing product system, developing alternatives, and then assessing the relative performance of the current system and alternatives, an analyst should gain a deep understanding of the merits and flaws of the alternatives. If one alternative is clearly superior to the others in many or all respects, then it is easy to see that switching to that alternative would probably result in an improvement. However, it is uncommon for one alternative to be superior to all others in all categories of interest. More likely, there will be trade-offs associated with the adoption of one alternative. For instance, a chemical substitution may be less toxic but require more energy to produce. Or, an alternative design may eliminate the use of a human carcinogen but introduce the use of an ecotoxicant. In almost every case, different alternatives will have different economic implications, both in ongoing costs and in the costs of making changes to an established production system. Public perceptions, corporate policies, occupational and environmental regulations, and stakeholder needs may also be relevant.

The complexity of this situation may make the selection of a course of action difficult. Decisions must often be based on a combination of quantitative and qualitative information. To add to the confusion, many assessment results are accompanied by a high level of uncertainty. This chapter discusses the tools and techniques available to assist an analyst in making, evaluating and justifying decisions regarding complex, multiattribute problems and uncertainty. While a complete review of these tools is far outside the scope of this report, this chapter is meant as a primer to identify directions of further study to interested readers. First, we discuss the nature of the decision problem of chemical alternatives analysis. Then we present a number of formal tools for analyzing decisions. These tools are often referred to collectively as "multiattribute decision analysis" or "multicriteria decision analysis." Finally, we outline a few extant implementations of decision support tools.

5.1 The Decision Problem

Decision analysis is a term for a collection of methods designed to assist and support systematic decision-making in situations of conflicting objectives, multiple stakeholders, and/or large uncertainty (Clemen, 1996). Selecting one preferred option from a set of alternatives is a decision problem. The possible options are likely to differ from one another in a number of ways. Information about the different options will come in many different forms, including quantitative results like costs, risks, and measures of technical performance along with qualitative information such as the presence and degree of different types of hazard, different manufacturing or supply chain requirements, and the applicability of different regulations. The relevant qualities of the alternatives are called "attributes" and a decision problem involving trade-offs among these different attributes is called a "multiattribute" or a "multicriteria" decision problem.

Different decision makers considering the same problem may come to different conclusions and suggest different courses of action. This is because selecting among alternatives that involve trade-offs is an inherently subjective process. A rational decision maker should weigh all the available information and choose the option that is most in line with his or her preferences. However, different attributes of a single alternative may conflict with one another, and in any case a decision maker's preferences may not be clear even to the decision maker him- or herself. When multiple stakeholders, all with their own ambiguous preferences, are impacted by a controversial decision it can be difficult for them to agree on a single course of action.

No decision-making tool exists that can resolve these challenges, which are inextricably tied to deliberative democracy and a free society. What decision theory does offer is an analytic framework for eliciting preferences and evaluating options. Like the name implies, a multicriteria decision problem comprises a set of options to consider and a set of criteria under which to evaluate the options. Decision makers can use whatever means they like to arrive at a preferred choice. In a deliberative context, in which multiple parties are working together to find an agreeable alternative, it can be helpful if the different parties agree on a common set of criteria on which to judge each alternative, although the relative importance of each criterion may vary from decision maker to decision maker.

Just as an alternative's attributes can be a mix of both qualitative and quantitative information, decision theory can involve the use of qualitative and quantitative techniques to arrive at a decision. Qualitative decision rules are any rules which do not involve recourse to a numerical score or a mathematical combination of attributes. Some examples include "weight of evidence" evaluations, threshold criteria (for example, toxicity must be below a certain grade of severity), elimination criteria (e.g. carcinogenic chemicals are not allowed), and heuristics or "rules of thumb" (e.g. air pollution is preferred over freshwater pollution; domestically produced products are preferred over imports). Quantitative rules, by contrast, are based on numerical calculations of scores or weights. Most formal

analytic tools for decision analysis depend ultimately on assigning a numerical score to each attribute under consideration, and then using a combination of mechanistic and interactive techniques to determine the relative "weights" of each score. When using these techniques, qualitative attributes will have to be put in quantitative terms.

5.2 Techniques for Decision Analysis

Decisions can be and are often made informally. That is, decisions can be made based on personal predilections or after discussions with staff. However, decisions made in a formal way, with documentation of the criteria considered and the reasoning behind the course of action that was selected, carry certain advantages. The process of decision analysis makes the decision maker's preferences explicit and allows the parameters of the decision to be observed, discussed and interpreted by other parties. This gives decisions reached with a formal framework a level of transparency and consistency that informal decisions lack. Decision making approaches which lack a formal basis may result in decisions which appear arbitrary to outsiders or to parties who disagree with the decision. In situations where there is a diversity of stakeholders, a formal decision making framework can serve as "documentation" of a decision, permitting parties in disagreement to come to terms.

Most existing research in decision theory has focused on quantitative tools (Clemen 1997). However, the concepts of qualitative decision making are easy to apply in practice. The Green Screen, developed by Clean Production Action, is an example of a decision framework based primarily on qualitative evaluations of chemicals (see section 4.4.1).

It is important to note that qualitative information can be used effectively in quantitative decision analysis through careful design of the decision problem. Qualitative information can be "quantified" as simply as putting it on a multiple-point scale. For example, a substance's toxicity can be ranked from one to five according to its classification in the Globally Harmonized System for chemical labeling (UN 2007). Other schemes can also be developed.

Generally, decision analytic techniques have three core components: a collection of choices or alternatives; a set of criteria or performance characteristics; and a system for comparing the former with respect to the latter. Most quantitative methods rely on assigning numerical scores to each alternative with respect to each criterion. Different alternatives are then compared according to the objectives of the decision makers, often through the use of numerical weights or weighting functions attached to each criterion. The scores are meant to indicate objective evaluations of the different options; the weights are meant to indicate the subjective preferences or goals of the decision makers.

Multicriteria decision analysis, or MCDA (also called multicriteria analysis or MCA) is a general term for the evaluation of complex problems with a decision-analytic approach.

Decision analysis in principle includes more specialized techniques, such as risk assessment, economic assessment, cost-benefit analysis or cost-effectiveness analysis. These specialized forms are limited in scope because each of them can only consider a specific type of information, such as risk or economic cost. MCDA stands in contrast to other methods because it is explicitly intended to take into account a broad array of different kinds of information. Specialized decision analytic techniques can provide support for MCDA but cannot replace it. For instance, it may be beneficial to use the results of a risk assessment study in performing an MCDA, but it would not be sensible to use the results of MCDA in performing a risk assessment.

MCDA is currently in wide use in business and government, but it remains a complex task requiring specialized training. It is widely varied, comprising a variety of techniques suitable for problems with different characteristics (Linkov et al., 2006b; Giove et al., 2009). The UK Department for Communities and Local Government has published a manual describing the use of MCDA for government and policy (UK DCLG, 2009). A more scholarly treatment of the subject can be found in the textbook by Belton and Stewart (2002).

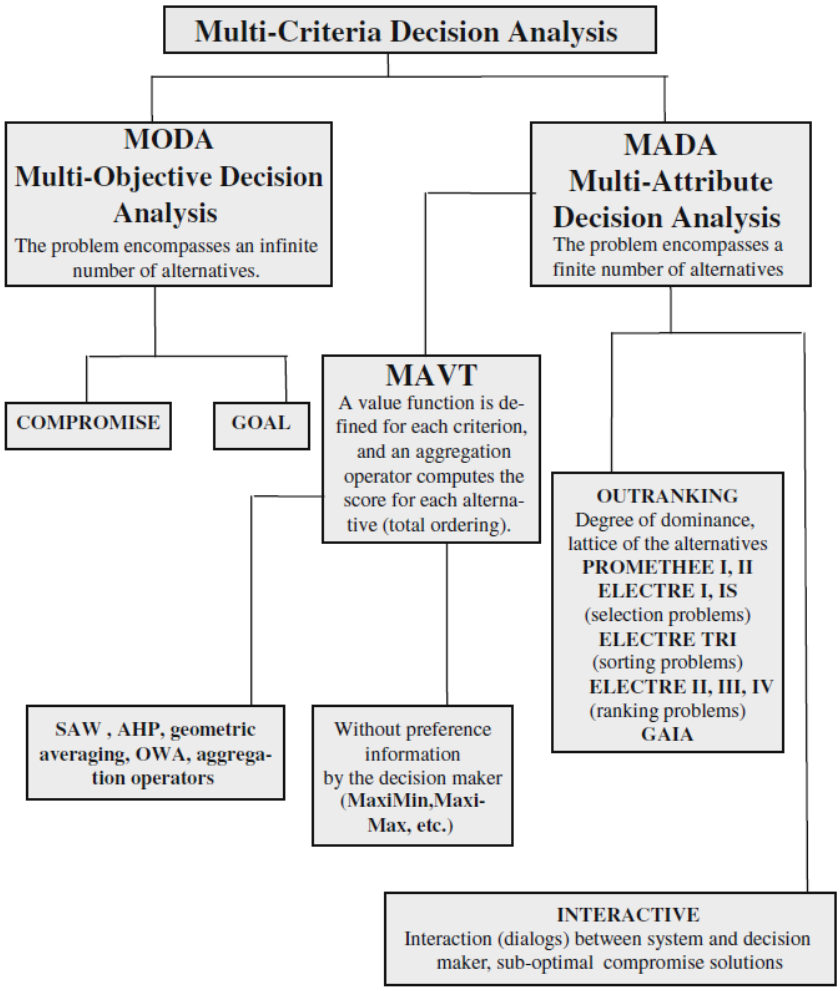
5.3 Basic Workings of MCDA

The process for conducting an MCDA could be described as follows:

1. Establish the decision context: aims, decision makers, constituents;
2. Identify alternative choices;
3. Identify criteria to evaluate the consequences of the alternatives;
4. Determine each alternative's performance under each criterion, optionally assigning numerical "scores";
5. Determine a "value" or other ranking for each alternative based on its scores on the different criteria;
6. Examine the results; conduct sensitivity analysis.

It should be emphasized that MCDA is a flexible and iterative process. It is not meant to produce a single "correct" answer which the decision makers must accept. Instead, it is meant to allow decision makers to explore different attributes of the decision problem and investigate the significance of their own aims and preferences. Decision-making criteria, the set of available alternatives, and even the decision makers' objectives themselves may change in response to information provided by the MCDA process. According to Belton and Stewart, "...the learning and understanding which results from engaging in the whole process of analysis is far more important than numerical results. The results should serve as a sounding board against which to test one's intuition" (Belton and Stewart, 2002, 119).

Figure 5.1: A classification of MCDA problems and methods (Giove et al., 2009).



5.3.1 Decision Criteria

One key element in MCDA is the selection of criteria for the evaluation of alternatives. It is important for all aspects of the problem to be represented in the criteria (the criteria should be "complete"). However, it is also important that the same aspects are not represented multiple times to avoid double-counting (the criteria should be "minimal"). All the different areas of concern should be well-represented (the criteria should be "balanced"). Above all, there must be a way to measure each alternative according to each criterion (the criteria must be "operational"). This measurement can be based on qualitative or quantitative evaluation, but in most cases it will ultimately be used to develop a numerical score.

5.3.2 Scoring and Valuing Alternatives

The most common MCDA techniques are designed to compute a single value (with or without uncertainty) for each of the alternatives under consideration. This approach has two parts: determining a score for each alternative in each criterion; and determining a value function which combines the scores together. Techniques in this family use a variety of different approaches to estimate scores and compute an appropriate valuation.

The simplest way to score an alternative's performance is to assess it directly, using physical measurements or expert judgments as the scores in each criterion. This approach can be enhanced by introducing principles from economic utility theory. According to this theory, two alternatives can be compared according to the expected utility they provide. Measurements of their performance can be adjusted by utility functions whose role is to estimate the expected utility that each measurement indicates. For instance, a home buyer may find that a larger house has greater utility than a smaller house, but that a 5,000-square-foot house does not provide very much more utility than a 2,500-square-foot house. If the home buyer were assessing possible houses using utility theory, he would want to select a utility function that represented his home-size preferences accurately. In MCDA, the utility functions for each criterion are generally called "partial value functions" or "partial utility functions," indicating that the overall utility comes from the combination of the parts.

Once scores are determined for each alternative in each criterion, each alternative may be ranked according to a valuation method which combines the scores together. The simplest valuation method is called the "linear additive model." In this approach each criterion is given a numerical weight which indicates its significance relative to the other criteria. The valuation of a given alternative is the weighted sum of that alternative's scores across all criteria. A low score in one criterion could be compensated by a high score in another. Variations on the linear additive model are a mainstay in MCDA, and many different techniques focus the effort on trying to estimate the preferences of the decision makers in order to determine appropriate scores and weights.

5.3.3 Sensitivity and Robustness Analysis

The outcome of a decision analysis as described above is a valuation of each alternative based on measurements of performance in each criterion, determination of scores from measurements, and the weighted combination of scores. Because many of these elements that enter into the decision analysis are subject to the decision makers' judgments, it is often useful to assess how the outcome of the process might change in response to changing inputs, known as sensitivity analysis. A related investigation, robustness analysis, studies whether the outcome of the model is reliable under conditions of uncertainty or different preference modeling.

Sensitivity analysis can be used to evaluate the relative significance of different criteria in the model's outcome and may indicate which aspects of the decision bear the greatest impact on the optimal solution. It may lead to a finding that small changes in preferences result in drastically different outcomes, or instead that the outcome is robust to small changes in decision-maker preferences. Individual stakeholders can use sensitivity analysis to determine the extent to which their needs and desires are represented in the outcome. Additionally, sensitivity analysis may provide unexpected insights into the operation of the model, potentially leading to the modification of scores or weights, the introduction of new alternatives or even a reconsideration of the aims and objectives of the decision analysis.

5.3.4 Other Methods

Other MCDA approaches exist which do not build primarily on economic utility theory. Two examples of these are outranking methods and goal programming.

Outranking methods are designed to focus on pair-wise comparisons of alternatives, and the goal in each comparison is to produce convincing quantitative evidence that one alternative is preferred over the other. Such an approach avoids the problems associated with estimating value functions for all alternatives, but introduces other problems in computational structure that make outranking difficult to implement. For a large number of alternatives, outranking becomes increasingly cumbersome because the number of pair-wise comparisons required increases quickly. And although value-function analysis is perhaps overly simplistic, it is much easier to grasp the relationship between inputs and outputs than in outranking methods. Belton and Stewart recommend that outranking methods be used as supporting analyses, but suggest that they are not well suited to public, multi-stakeholder discussions (Belton and Stewart, 2002, 259).

Goal programming methods are based on the principle of satisficing, in which alternatives are ruled out depending on their performance on a single, key criterion. All alternatives which do not meet some minimal standard or goal are discarded; the remaining options are then considered with respect to the next most important criterion; and the process continues until only one alternative remains. Implementations of goal programming methods require sophisticated computational techniques. Goal programming may be most valuable as a screening method to rule out nonviable alternatives before traditional value-function MCDA is performed.

5.3.5 Advantages and Disadvantages of MCDA

The primary benefits of MCDA are the consistency and transparency achieved through using a precise and rigorous decision-making methodology. Through sensitivity analysis, the influences of different criteria and preferences can be observed. MCDA provides

a framework for reconciling information from many different types of analysis, including direct measurement, risk assessment, economic evaluations, estimates of intangible quantities and qualitative preferences. Analysis with MCDA also lends itself well to "adaptive management," in which decisions are constantly revised with new interpretations, new data, and advice of stakeholder groups (Linkov et al., 2006a). MCDA can handle quantitative results of life cycle impact assessment in a straightforward manner, though the use of MCDA does not reduce the essential complexity of interpreting life cycle results (Reap et al., 2008).

The drawbacks of MCDA are mostly a consequence of its highly technical nature. Though it incorporates a broad array of different types of information, that information must be put in numerical form before it can be used in a decision model. The selection of weights has outsize importance on the outcome of the decision analysis. MCDA requires a high level of theoretical sophistication to use, and is only suitable for application by experts trained in its techniques. Finally, because MCDA is an integrative process, highly dependent on the context in which it is applied, it is difficult to generalize its properties and nearly impossible to create guidelines for its general implementation.

In the context of alternatives analysis, MCDA is extremely well suited to the task of evaluating alternatives. It may be an invaluable tool. However, the success of its use depends primarily on the rigor and robustness with which its principles are applied. Done well, MCDA can provide both specific and far-reaching insights into the complexities of a problem as well as the preferences of decision makers and stakeholders. However, MCDA is not intended to produce a single "correct" result or synthesize a reliable or defensible conclusion. Instead, it should be used to foster improved understanding, rationality and transparency. It is a decision making aid, not a substitute for a decision maker.

5.4 The Analytic Hierarchy Process

The Analytic Hierarchy Process (AHP) is one of the most popular MCDA techniques, although it was developed independently of mainstream decision analysis and is regarded critically by some MCDA practitioners because of its ambiguous theoretical foundations. AHP is described as "a general theory of measurement" by its inventor (Saaty, 1987). Ultimately, AHP arrives at its outcomes through computation of an additive preference function, which makes it similar to value-function methods. However, its approach is to elicit the preferences of a decision maker through a series of pair-wise comparisons of judgment criteria, followed by pair-wise comparisons of different alternatives. This contrasts with outranking methods, which only involve comparisons of alternatives. The use of AHP for environmental assessment is discussed by a number of researchers (Banai-Kashani, 1989; Ramanathan, 2001; Wolfslehner et al., 2005).

Analysis with AHP requires the construction of a hierarchical value tree containing the cri-

teria and sub-criteria for judging the alternatives under consideration. All the elements at a given level of the hierarchy should be of comparable scope. The decision maker is prompted to rank the importance of the criteria relative to each other on a qualitative scale (Saaty uses a nine-point scale, ranging from "equal importance" to "extreme importance of one over the other"). The consistency of the decision maker's choices can be determined through a simple computation. Saaty notes that some amount of inconsistency is valuable because "...without it new knowledge which changes preference order cannot be admitted. Assuming all knowledge to be consistent contradicts experience which requires continued adjustment in understanding." (Saaty, 1987, 172). If the matrix of preferences is found to be excessively inconsistent, the rankings may be elicited again after further study, leading the decision maker to refine his or her preferences.

Implementation of the process requires two main steps: determining the relative weights of the sub-criteria, and determining the scores of the alternatives. At each stage the process is the same: build a preference matrix by comparing pairs of elements, be they criteria or alternatives. The preference matrix is converted into a set of weights (in the case of comparing criteria) or a set of scores (in the case of comparing alternatives) using a straightforward computational method. The scores and weights are then combined to achieve a valuation of each alternative.

AHP is simple to use, which probably accounts for its popularity. However, it has also been the subject of debate among practitioners (Belton and Stewart, 2002, 157). The major objection to AHP is that it can lead to a phenomenon of "rank reversal." In a decision problem, it may be found that option A is preferred over option B. Rank reversal means that the addition of a third option, C, may result in a reversal of A and B, i.e. B now being preferred over A, even with no changes to the nature of options A and B. Such a result, according to some commentators, suggests that the AHP is an inherently inconsistent method. Proponents of AHP counter that rank reversal occurs only in exceptional circumstances.

Additionally, AHP uses a ratio-metric scale as the basis of its computations, meaning that comparison of one element over another is described as a ratio, such as "A is n times more important than B." Use of such a scale implies that elements are being compared in terms of their distance from a "zero" point, as in "A is n times farther away than B." This is considered problematic by some commentators. More traditional MCDA techniques use interval scales, in which two independent reference points define a scale. Distance along the scale forms the preference measurement. Modifications of AHP that address this critique are available (Saaty and Vargas, 1987), though use of the original ratio-metric model predominates.

5.5 Examples

5.5.1 Cradle to Cradle Design Protocol

Cradle to Cradle design (C2C), developed by the consultancy McDonough Braungart Design Chemistry (MBDC), began as a proprietary product certification system but has recently been released to the Green Products Innovation Institute (see Section 3.4). A basic tenet of MBDC (and of the C2C protocol) is the notion that incremental changes performed in the name of "sustainability" are inadequate to the task of radical transformation demanded by the current industrial paradigm (MBDC 2008). C2C looks to the biological metabolism of nature as a model for human industry, or "technical metabolism," to strive for. Products or materials that cannot be metabolized by the natural world should never enter it; by the same token, technical materials that have reached the end of their useful life should be recoverable as "nutrients" for the next production cycle.

The design protocol has three fundamental elements:

- "Waste equals food" – Products and materials should be designed to be used repeatedly and to be safe. Products at the end of their useful life should be recognized as having value to be recovered.
- "Use current solar income" – The energy used in productive activity should be supplied from renewable sources.
- "Celebrate diversity" – Promote healthy ecosystems through careful management of water and other natural resources; operate in a socially responsible manner.

The protocol implements these elements in the form of binary evaluation criteria (that is, each criterion either is or is not met). A product system that is evaluated must meet a certain subset of these criteria to receive a "basic" certification; more stringent requirements are added to reach "silver," "gold," and "platinum" certification. A product is required to be re-certified on an annual basis in order to maintain the certification, ensuring the client's commitment to the program's goals.

Evaluation criteria are grouped into categories of "Material Health", "Material Reutilization / Design for Environment", "Energy", "Water", and "Social Responsibility." A mix of qualitative and quantitative metrics is used. Most criteria relevant to CAA are included in the "Material Health" category, which classifies each substance used in the product as "green" (little to no risk), "yellow" (low to moderate risk), "red" (high hazard and risk), or "grey" (incomplete data). Substances are evaluated based on human health criteria, environmental health criteria, and material class criteria, the latter of which specifies certain chemical classes which always receive the "red" certification. Substances which are "grey" must be fully assessed within six months of certification or they become re-classified as "red." "Red" substances must eventually be phased out.

The C2C program is a rigorous test of a product's sustainability according to one model of environmental performance. The requirements for certification are stringent and demanding, to the point that few products are eligible for certification. The C2C protocol thus provides an ambitious target for reshaping industrial operations. A widespread adoption of the C2C principles would have a dramatic effect on product design and manufacturing.

5.5.2 GoodGuide

http://www.goodguide.com

GoodGuide is a for-profit company that produces an online consumer resource, also called "GoodGuide", intended to help consumers identify superior products. GoodGuide describes itself as a "for-benefit" company and identifies as a "B Corporation," certified by the non-profit B Lab as a "purpose-driven" company which "uses the power of business to solve social and environmental problems."[1] GoodGuide provides access to a database of consumer products which are ranked according to the product's or manufacturing company's performance in the categories of health, environment, and society. The company has targeted Internet-savvy customers, providing an online forum for user discussion and placing links to popular social media outlets like Twitter and Facebook on its homepage. It has developed an iPhone application which can identify products by barcode and provide information to consumers as they shop.

The rating tool itself, which is accessed over the Internet, implements a proprietary multicriteria decision algorithm to assign products a set of three scores in categories of health, environment, and society. The algorithm includes a list of over 1,100 indicator criteria arranged into an informatics framework called an "ontology," which is a formal representation of the relationships among concepts and ideas. Data are collected from a diversity of sources including government agencies, scientific institutions, NGOs, commercial data providers, and product manufacturers. GoodGuide personnel review the data for each product and assign scores, ranging from 0–10, in each applicable indicator category, according to unpublished rules. The scores are then combined using the multicriteria decision algorithm to result in a 0–10 rating in each of the three main categories (health, environment, society). Those three category scores are also weighted and combined into a single overall score. When viewing the rating for a particular product, a website user can "drill down" into the score to inspect the product's scores on each indicator criterion that was included, as well as the data provider which provided the information that led to the assigned score. Quite often the data provider is GoodGuide itself.

Criteria regarding a product's composition and use of toxics are included in the "health" category. The GoodGuide methodology distinguishes between "suspected" and "recognized" health risks. "Recognized" health risks identified by authoritative agencies such

[1] See the B Lab website: http://www.bcorporation.net/about.

as the US EPA, or listed on authoritative lists such as the California Proposition 65 list (see section 2.3.1). "Suspected" health risks are identified in scientific literature or major toxicology databases as being potentially hazardous. A single "recognized" health risk is sufficient for a product to be given a "high level of concern," the most precautionary categorization. The GoodGuide documentation notes that the existence of controversy surrounding a chemical or substance is not sufficient to affect the score of a product containing that substance. With very few exceptions, a product's environmental and social scores are based on the aggregate performance of the company that produces it and not the characteristics of the product itself.

A lack of sufficient data is a significant problem to a rating tool with a broad inclusion of products like GoodGuide. GoodGuide relies primarily on data voluntarily provided by product manufacturers to fill data gaps; however, when there is a gap and the company does not provide information, the algorithm places a "cap" on the maximum score the product is eligible to receive. This creates an incentive for companies to provide data as long as the "correct" score for their product is higher than the cap.

The lack of publicly available information about how scores are developed is the tool's greatest weakness. The company does not provide any published reports, documentation, or whitepapers describing its decision algorithm. The documentation provided on the website is vague and does not explain how the category scores are derived or how the tool processes them into ratings, with the exception of a few examples. The company has an interest in maintaining the secrecy of its algorithm in order to prevent product manufacturers from "gaming" the algorithm to produce preferential scores. However, as a consequence the tool has very little transparency, causing its results to have questionable veracity. In addition, product ratings are developed on a relative scale, not an absolute scale. In other words, a product is scored in comparison to similar products, rather than based on any independent set of criteria. Thus a preferential rating may indicate that a product is safer than a competitor, but may not indicate that the product is actually "safe." Finally, the distillation of 1,100 indicator criteria into a single 10-point score reflects a substantial reliance on internal value judgments by GoodGuide staff that may or may not reflect either customer preferences or true hazards and risks.

The tool's social media and mobile Internet features make it a powerful way to inform and influence consumer behavior, but the accuracy or appropriateness of specific ratings cannot be known. A platform like GoodGuide may, however, be well positioned to incorporate the contents of a toxics clearinghouse or online public database of safer alternatives.

5.5.3 Pollution Prevention Options Assessment System (P2OASys)

http://www.turi.org/toxics_use_home/hot_topics/cleaner_production/

The P2OASys tool is a special-purpose Microsoft Excel spreadsheet which is intended to facilitate the side-by-side comparison of hazard information for a base technology and up to three alternatives. It consists of a particular decision-analytic framework built into a set of worksheets and Microsoft Visual Basic macros inside the spreadsheet. Its intended use is for an end-user to input quantitative information about the base case and alternatives into the worksheet, and then to view the results of the decision analysis on a comparison page.

The P2OASys spreadsheet includes criteria for acute and chronic human health effects, physical hazards, aquatic hazards, atmospheric hazards, persistence / bio-accumulation, hazards relating to chemical exposure, disposal, and product use, and energy and resource consumption. The base case and alternatives are characterized in terms of the percent composition of the different chemical compounds that make them up. The user scores each chemical component in each criterion, and also provides a measure of "certainty" which ranges from 0-100%. In some cases the ranking is qualitative (e.g. Low, Medium, or High exposure potential). The quantitative process which is used by the spreadsheet to score the alternatives is not clear.

P2OASys represents an implementation of a specific multicriteria decision analysis algorithm. The exact algorithm used is encoded into the spreadsheet itself. Because the MCDA process includes both subjective and objective evaluations, it is not immediately clear what value judgments were incorporated into the algorithm by its authors. P2OASys may be useful in certain circumstances as a decision framework, particularly when it is used along with consultation from its authors. In most cases, however, it is more likely to be useful as a checklist of hazard information that should be gathered. It may also have value as an example of MCDA in application, or as a model implementation of a decision support tool in an interactive spreadsheet.

Chapter 6

Implementing Chemical Alternatives Analysis

The objective of a chemical alternatives analysis (CAA) is to present a comprehensive review of practical options for reducing the hazards associated with a given product system. The starting point for performing any alternatives analysis is the recognition of a hazardous or potentially hazardous situation. For CAA specifically, the hazardous situation is brought about by the presence of a toxic chemical. In this chapter, the hazards presented by this chemical are referred to as the "primary concern" because they are the reasons for carrying out the analysis. The objective of CAA is to develop and study a variety of potential ways to reduce hazards and/or risks associated with the primary concern while avoiding unintended or regrettable consequences and possibly receiving outside benefits.

This chapter discusses some general considerations for implementing a regulatory program of chemical alternatives assessment. First, we describe the general procedure for carrying out a CAA. Then we present briefly several case studies of alternatives assessments.

6.1 General Guidelines

The process has three main phases, which should be undertaken within a framework of iteration, revision, and continuous improvement, involving stakeholders where appropriate:

1. Product Phase. Describe the product system and develop alternatives.

2. Assessment Phase. Evaluate the current situation and possible alternatives:
   - do they address the reason for concern?
   - what are their potential benefits and regrets relative to the current situation?
3. Decision Phase. Identify feasible alternatives and select a course of action based on the results of the analysis.

In this section each phase of the process will be examined. This section describes a set of general guidelines for performing an effective CAA, discusses some aspects of compliance in a regulatory context and efficacy of regulations, and presents case studies of alternatives assessments performed by public agencies.

Phase 1: Describe the Product System and Develop Alternatives

A CAA is usually conducted in the context of a specific product system, and often a specific chemical of concern. The first step in conducting a CAA is to describe the product system under study and relate the chemical of concern to the product. This description should include an account of what the product does as well as how it is manufactured. A product typically serves a specific function or provides a specific service to a consumer. What does it do? How does the use of the chemical of concern contribute to achieving that functional use? Where are the sources of potential exposure to the chemical of concern or to other potential hazards? A clear understanding of the product's function is necessary to develop a comprehensive set of alternatives to consider. The performance of the product system should be described in quantitative terms. The reason for this is so that the performance of possible alternatives can be characterized and compared to the base system.

Alternatives should then be developed which in some way address the primary concern. Potential alternatives are defined very broadly (Figure 6.1). Alternatives can be any means of achieving a comparable functionality by changing the way the product is made or used. They may include substitution of one chemical for another, product reformulations which eliminate the need for the chemical of concern, process changes to reduce reliance on a chemical or reduce exposure to that chemical, product or process redesigns to change the way the chemical is used or eliminate it, or management changes which improve handling of the chemical to allow less of it to be lost as waste or in environmental emissions. Alternatives that reduce or eliminate the use of toxics should be considered, as well as options to reduce exposure.

It is important to maintain a broad viewpoint in considering potential alternatives. While simple chemical substitutions are the easiest alternatives to implement, it may be that no direct substitution is available, or that equivalent chemicals all have problems with toxicity. Considering a wider scope of potential alternatives increases the likelihood that a safer alternative is found. Some alternatives may be under development but not currently

Figure 6.1: Different alternatives to be considered.

Different kinds of alternatives:

Chemical Substitution	–	Substituting a less-toxic chemical for the chemical of concern.
Management Changes	–	Improving control of the chemical of concern to lessen exposure, reduce environmental emissions, or increase recycling.
Product Reformulation	–	Changing the makeup of the product so as not to require the chemical of concern.
Process Changes	–	Changing how the product is manufactured to reduce or eliminate the need for the chemical of concern.
Product Redesign	–	Changing how the product is built, shaped, assembled, or used to reduce or eliminate the need for the chemical of concern.

available—these should also be considered. Minor product redesigns may be possible which eliminate the need for any toxic chemicals. For completeness, the alternative of ceasing to produce the product in favor of an alternative way of meeting the functional use should also be considered.

The outcome of step 1 is a description of the existing product system as well as a list of potentially viable alternatives for reducing the hazards posed by the chemical of concern. In the next step, several, if not all, of these alternatives should be assessed to determine their relative performance.

Phase 2: Alternatives Assessment

Once a number of potentially viable alternatives has been developed, it is necessary to evaluate them against the current situation. The evaluation of potential alternatives in order to understand their benefits and drawbacks is the essential objective of alternatives assessment, which was described in Chapter 3. In this evaluation there are two main goals. The first goal is to address the reason for performing the CAA: to reduce the hazards and/or risks presented by the use of a chemical of concern through the adoption of safer alternatives. Second, it is desirable to understand the potential benefits and regrets that could arise from selecting a potentially safer alternative. The alternatives assessment is motivated by the dual objectives of addressing the primary concern and understanding potential benefits and regrets.

The evaluation should be broad, encompassing the full life cycle of the product and including a comprehensive set of evaluation categories. These categories should include technical performance, economic viability, toxicity characteristics, environmental impact, effects on the consumer and public health, resource consumption, and impacts on ecosystems and endangered species, as well as any other areas that are relevant to stakeholders. Other existing tools, such as risk assessment and cost-benefit analysis, should

also be incorporated into the alternatives assessment. Because there are potentially limitless categories to consider, it is important to select the categories which are most relevant to the product system under study. Some existing alternatives assessment frameworks, including CTSA and the Lowell Center Framework (See Chapter 3), have adopted a modular approach to evaluation of alternatives, emphasizing the variety of concerns that may be relevant to a given product or a particular situation. A broader, more diverse evaluation will increase the likelihood of identifying the significant impacts of the product system and alternatives, including potential benefits and regrets. Finally, the current situation and all alternatives should be considered at the same level of detail so that they can be compared on equal footing.

In carrying out an evaluation of an existing product system and possible alternatives, it is often valuable to construct a model of the product's life cycle (Figure 3.2). A life cycle model starts with a representation of a product's complete supply chain, from extraction of raw materials through manufacture and formulation, and distribution. To the supply chain model, add consumer use, and product recovery and disposal at the end of the product's life. A fragmentary model which includes only part of the life cycle can still be valuable during alternatives assessment. An analyst familiar with a specific product system can quickly assemble a rough model of the product's life cycle based on his or her familiarity with the product's supply chain. Some research may be necessary to understand what happens to the product when the consumer is using it and at the end of its life.

Construction of a life cycle model for the product's current situation as well as for each alternative will help clarify the significant differences between the current system and the alternatives, ensure that life cycle stages that occur upstream and downstream of product manufacture are considered, and illustrate opportunities for alternative approaches. The alternatives assessment should focus on the aspects of the life cycle that differ among the various alternatives under consideration. At each life cycle stage, the significant hazards, toxics exposures and risks, as well as human health, environmental and economic impacts can be assessed.

The analysis may also benefit from expanding the life cycle model into a full Life Cycle Assessment (LCA; see Section 3.5). Performing a life cycle assessment is a robust way to identify potential external impacts and risks. Even in the absence of quantitative data, the modeling approach embodied in the goal and scope portion of an LCA can be a valuable tool for understanding a product system. In particular, the concepts of the functional unit, the network of industrial processes, and the system boundary all have direct relevance to alternatives analysis. A preliminary LCA which includes these aspects can provide an excellent complement to other tools for alternatives analysis.

The alternatives assessment is a broad, modular, open-ended approach to gathering information about the performance of the current system and the alternative approaches.

The outcome of step 2 is a detailed description of each option under consideration, presented in a way that describes the relevance of each alternative to the original reason for concern (the use of the toxic chemical of concern) and also captures any expected benefits and drawbacks of the alternative. Often these results can be summarized in a table which shows the relative performance of each option in each category of consideration. A clear statement of the results of step 2 may be a useful document for communicating with stakeholders and regulators about the nature and viability of different alternatives.

Phase 3: Selecting a Course of Action

The outcome of an alternatives assessment is "data-rich" in the sense that information has been gathered from a wide variety of sources and stakeholders. The results of many different assessments, such as economic analysis, risk assessment, and life cycle assessment, are pooled together into a single reservoir of information about the current situation and a number of potentially viable alternatives. During the course of alternatives assessment, some of the potential benefits and drawbacks of each alternative should become clear to the analyst and participating stakeholders. Decision makers must now select a course of action.

A company's operations cannot be reconfigured instantly. Because manufacturing a product is a complex process involving capital investment, supply chain management and consumer attitudes, the process of transitioning to a safer alternative must be gradual and measured. The course of action should include a combination of adoption and adaptation: moving toward adopting one or more alternatives and adapting the existing system to make use of knowledge gained in the assessment process. The following are some points to consider which may improve the robustness of a decision.

- Careful Documentation

Among the most important signs of a good decision is that it stands up under scrutiny. Decision makers should look to the decision analysis portion of CAA as a way to document the decision-making process so that other stakeholders within the organization as well as regulators and the public can understand it. The selection of a course of action must be made transparently, with a clear set of criteria and a well-reasoned argument defending the ultimate choice. Dissenting opinions, if they have merit, should also be included along with their justifications (Belton and Stewart, 2002; Department for Communities and Local Government, 2009).

- Selection of criteria

As discussed in section 5.3.1, the set of criteria under which each alternative is considered should be complete, minimal, balanced, and operational. In other words, all significant

aspects of the problem should be represented by the criteria, none should be "double-counted" or included twice, each criterion should be considered in approximately equal depth, and it must be possible to make a meaningful evaluation of each alternative according to each criterion. For CAA specifically, criteria should broadly include hazards to human health, hazards to ecology and ecosystems, impacts of resource depletion and environmental degradation, as well as technical performance and economic cost. It may be appropriate to assign elevated importance to the primary concern of the analysis.

- Mitigation opportunities

The existing system and alternatives will have different benefits and drawbacks. Some benefits and drawbacks may not be directly related to the primary concern of the analysis. In cases where an alternative choice presents significant benefits in the area of primary concern but also carries trade-offs in the form of substantial drawbacks elsewhere, it is important to consider options for mitigating these drawbacks through different management practices. It may be that yet further benefits can be found through careful implementation of the alternative choice.

- Routine reassessment

The decision need not be monolithic (i.e. a gigantic shift all at once) and should not be regarded as final. Instead, chemical alternatives analysis should be undertaken as part of a program for self-assessment and continuous improvement. Rather than making an abrupt change in direction, it may be more appropriate to consider a gradual phase-in of a preferable alternative in combination with ongoing efforts to improve understanding of the product system's benefits, drawbacks, and environmental impacts. By the same token, alternative courses of action which were not selected should be reconsidered in the future as their viability may evolve with the business or technology landscape.

6.2 Alternatives Analysis In Practice – Case Studies

Alternatives analysis is largely a new area of inquiry, but a number of public agencies have implemented programs promoting alternatives assessment or performed studies which included it. In this section we summarize the motivations, methodology, and results of the efforts of three different agencies in assessing and reducing hazards from toxic chemicals through the systematic evaluation of alternatives. We focus on the identification of the functional unit, on the process used to select among alternatives, and on the inclusion of life cycle impacts.

6.2.1 TURI – Five Chemicals Study, 2006

In July 2005 the Massachusetts legislature asked the Massachusetts Toxics Use Reduction Institute to prepare an alternatives assessment study of five common toxic chemicals: lead, formaldehyde, perchloroethylene (PCE), hexavalent chromium, and di (2-ethylhexyl) phthalate (DEHP) (Massachusetts Toxics Use Reduction Institute, 2006). The purpose of the study was to identify significant uses of each chemical in Massachusetts, determine likely environmental and health hazards, and understand the potential for reduction of hazards through the adoption of alternative chemicals or technologies. The institute was also mandated to evaluate the feasibility, costs and potential impacts on "economic competitiveness" of adopting the alternatives. The project had a total budget of $250,000 and was completed in 2006.

The five chemicals were investigated concurrently by five independent teams operating according to a common methodology. In total, 16 distinct product systems using the five chemicals were assessed. In nearly every case an alternative was found which was both readily available and likely to reduce environmental hazards. Many of the alternatives were also judged to be economically competitive, although the study report emphasized that any specific implementation plan should include a more focused economic analysis.

The approach taken by the institute included three phases. Because the scope of the investigation was so broad, covering all uses of a chemical throughout the state, it was necessary to first identify priority uses of each chemical for analysis, which made up phase 1 of the project. This was accomplished through a material flow approach, using data from the EPA Toxics Release Inventory (TRI) and data collected through TURA, along with expert judgments of stakeholders, to identify major uses for each chemical which were sources of potential hazards. Rather than focus solely on the largest-volume users, the study authors selected product systems based on four criteria:

- Importance to Massachusetts, either through use in manufacturing or in consumer products;
- potential availability of alternatives;

- exposure potential;
- potential value of the alternatives assessment to the people of Massachusetts, as represented by stakeholders in attendance at process meetings.

The analysts selected three or four product systems for in-depth analysis for each chemical under study.

Phase 2 was the identification of possible alternatives in each use case, including drop-in chemical substitutes, changes in materials, changes in manufacturing operations, design changes, and novel technological approaches. Potential alternatives were determined, again, through extensive involvement of stakeholders. Chemical ingredients in the alternatives were screened according to the EPA's PBT profiler tool to rule out hazardous substitutions, and then prioritized for assessment. Three to eight high-priority alternatives were selected for each product system.

Phase 3 comprised the alternatives assessment. The base case and alternatives were evaluated for technical feasibility, economic feasibility, and environmental and human health. An important aspect of the TURI methodology was the selection of objective, quantitative performance metrics for evaluating technical feasibility. The alternatives could then be directly compared to the base case by looking at their performance. For the assessment itself, the TURI team relied on published results and stakeholder input. The analysts performed no toxicological data collection or laboratory testing.

Conclusions

The Five Chemicals study found that in every case studied there was at least one feasible alternative to the toxic chemical that would be likely to meet the technical needs of end users and reduce hazards to health and the environment. Regarding cost-effectiveness, many alternatives were cost-competitive with their toxic counterparts, though some were more expensive. The report observed that many alternatives based on emerging technologies may be subject to changing economic conditions as the technologies develop. Finally, the report discussed the fact that much less data are generally available on alternative practices than established practices, merely because established practices are far more familiar. As a consequence, some results of the assessment may be subject to large uncertainty. The report identified six specific recommendations for further study and implementation.

The study relied heavily on close collaboration with a wide array of industry and non-governmental stakeholders who provided technical input regarding uses and properties of chemicals and possible alternatives. The involvement of industry stakeholders was one of the guiding principles in the study's design, and was considered "key to the success of [the] project" (p. 458). The project also emphasized transparency of process and results,

Figure 6.2: The results of TURI's alternatives assessment for lead ammunition (Massachusetts Toxics Use Reduction Institute, 2006).

Table 3.4.1 J: Assessment Summary – Alternatives for Lead Ammunition/ Shooting Ranges

Assessment Criteria		Lead (Reference)	Comparison Relative to Lead				
			Bismuth	Copper	Iron	Tungsten	Zinc
Technical/ Performance Criteria	Density	11.34 g/cm^3	-	-	-	+	-
	Frangibility	No	+	+	+	+	?
	Barrel Wear	Good	=	=	=	?	=
Environmental Criteria	Primary Drinking Water Standards (MCL Action Level)	15 µg/L	?	+	+	?	?
	Aquatic Toxicity: Water Quality Criteria (CMC)						
	Freshwater	65 µg/L	?	-	+	?	+
	Saltwater	210 µg/L	?	-	+	?	-
Human Health Criteria	Occupational Exposure: REL (8-hour TWA)	0.050 mg/m^3	?	+	+	+	+
	Carcinogenicity	EPA B2 IARC 2B	+	+	+	+	+
	Developmental Toxicity	Yes (Prop 65)	+	+	+	+	+
Cost	Cost/9mm round	$0.14-$0.20	-	-	-	-	-
	Operating Costs	High	+	+	+	+	+

Comparison Key + Better = Similar - Worse ? Unknown

a focus it also considered "essential" to a viable alternatives assessment. According to the authors, transparency in reporting enabled stakeholders and the general public to gain knowledge of different techniques to reduce hazards related to the five chemicals studied.

TURI clearly intended its study to serve as a model for future alternatives assessments performed by other agencies, but the authors recognized that simply offering an example is inadequate. The report observed that various agencies performing alternatives assessments all use their own slightly different approaches, and suggested that the utility of alternatives assessment would be improved by a common approach. It recommended that an "international working group be convened to establish . . . a standard alternatives assessment methodology." It is conceivable that such an endeavor would result in a guidance document similar to ISO-14044 (International Organization for Standardization, 2006), which governs life cycle assessment.

Identifying the Functional Unit

The process of determining the functional unit for analysis happened explicitly early in the study. Initially the scope of investigation was all uses of each chemical in the state, but the analysts whittled down the field to a small number of product systems, which the authors called "uses" of the chemical. It is not clear how the specific product systems, called "priority uses," were ultimately selected for analysis. Once selected they were carefully defined through the identification of specific, quantitative measures of performance. For instance, the use of PCE for dry-cleaning was characterized in terms of operating time, load capacity, cleaning quality (qualitative), garment compatibility, spotting and post-handling time, and recycling (qualitative).

The functional unit was then defined as the base case's performance on each of the technical performance criteria. The alternatives could be scored according to the same criteria, and so they could be directly compared. In this approach, the selection of performance criteria for evaluation is equivalent to the definition of the chemical's functionality; the functional unit could be described as the scores of the base-case chemical in these criteria.

Evaluation and Selection of Alternatives

Once all alternatives were identified and all criteria for consideration was defined, assessment of alternatives could be performed simply by scoring each alternative in each criterion. This is made much simpler through the formal definition of technical performance criteria.

The study's practitioners did not present a methodology for choosing among alternatives. Instead, the outcome of the study was a table of performance scores, showing the performance of the base case alongside the performance of the alternatives in each criterion. These alternatives assessment summary tables were qualitative in nature, using the symbols +, – , =, and ? to indicate each alternative's performance relative to the base case. The study's authors explicitly did not include any ranking of alternatives, instead considering the tabular comparison of scores to be the most valuable way to present the results of the study. Figure 6.2 shows the results of one assessment in tabular form.

Treatment of Life Cycle Impacts

Formal life cycle assessment was not part of this alternatives assessment study. In place of considering the full life cycle impacts of product systems and alternatives, the study included "readily available" information on "key life cycle considerations" (p. 60), which were discussed in a qualitative fashion in the report. The alternatives assessment summary tables made mention of life cycle impacts only in cases where the study authors

judged them to be relevant. For instance, "Volume of waste generated" is listed as a criterion for considering alternatives to hard chromium electroplating of industrial components. However, because life cycle information was included only anecdotally, it is possible that potential regrets associated with certain alternatives may have gone undetected in the TURI report.

Cost of the Study

The Five Chemicals study had a total budget of $250,000 and included comprehensive assessments of 16 different product systems and their alternatives. Thus, the average cost of an alternatives assessment for a single product system under their methodology is in the neighborhood of $15,000-20,000. Because TURI is an expert organization with nearly 20 years' experience with alternatives assessment, this figure reflects the cost that might be incurred by a third-party consultant who was contracted to perform a routine alternatives assessment on a state-wide scale. It may not be an accurate estimate of the cost for a firm to perform its own assessment.

6.2.2 US EPA – Design for Environment Program

In the mid-1990s the EPA began its Design for Environment (DfE) program as a series of voluntary partnerships with businesses to reduce risk through pollution prevention and to identify and implement strategies for improved environmental performance. The DfE program included 18 partnerships, of which 4 are still ongoing. Some of these projects took the form of alternatives assessments, presenting industry participants with the opportunity and challenge to adopt safer practices in their use of chemicals. The DfE program bears some resemblance to TURI because both involve partnerships with industry actors. However, the TURI effort focused primarily on reducing the volume of specific chemicals, whereas the EPA program was more oriented towards risk management of specific processes.

Below we discuss two DfE alternatives assessment programs. The Printed Wiring Board partnership produced two alternatives assessments, one for surface-finishing of printed wiring boards (PWBs) and one for making holes conductive (MHC). Both these assessments used the Cleaner Technologies Substitutes Assessment (CTSA) methodology (discussed in Section 3.1 above). The modular approach inherent to CTSA was highly visible in both studies. The outcomes of the studies demonstrate that modularity can be a powerful method for assembling a wide array of information.

Printed Wiring Boards – CTSA Alternatives Assessments, 1998-2001

The EPA presented two parallel CTSA studies on the manufacturing of printed wiring boards (PWBs), one focused on surface finishing (Geibig and Swanson, 2001) and the

other focused on making holes conductive (MHC), also known as "through-hole plating" (Kincaid et al., 1998). In the CTSA framework, surface finishing and MHC comprise two different "use clusters" (see Section 3.1 above). The essential challenge on the industry standard surface finishing technology at the time was its reliance on lead-based solders and its generation of large amounts of waste. The issues with MHC are that is highly chemical-intensive and generates large quantities of industrial wastewater. Both studies used industry input to identify and characterize possible alternatives.

The outcomes of the surface finishing study were unclear and did not result in any recommendations. The executive summary presented a summary of the alternatives in chart form which seemed to indicate one alternative which was either equivalent or superior to the base case in every category. In the case of MHC, the study found that all alternatives appeared to be superior to the base case, and that three alternatives were superior in every category. The study recommended transitioning to any of the alternatives, but cautioned that some chemical hazard information was omitted because some proprietary chemicals were not disclosed.

Identifying the Functional Unit

In the CTSA framework, the functional unit is defined by the "use cluster," and it is left to expert judgment to identify what features of the base system are required in the alternatives. Because both use clusters were standard parts of PWB manufacture, the functional unit was self evident for these studies. Performance of the alternative is assessed as one of the analysis modules, "performance assessment," in the Competitiveness module group. In both of these studies, performance was assessed at actual production facilities where the alternative processes were in use. Notably, the "use cluster" approach to defining the functional unit limits the scope of potential alternatives.

Evaluation and Selection of Alternatives

The CTSA methodology explicitly does not include recommendations for ranking alternatives or for selecting a preferred alternative. Its purpose is to facilitate the generation of information, leaving the decision makers to make use of it however they see fit. One weakness of the CTSA methodology is that it does not offer a routine way to present the results of the assessment – neither of the case studies contained a concluding chapter. Instead, the outcomes of each module were presented independently in the chapter entitled "Choosing among technologies." Given the copious amounts of data presented, the CTSA methodology would benefit from the inclusion of a final synthesis stage in which the results are combined into a summary.

Treatment of Life Cycle Impacts

Life cycle resource consumption is included among the analytic modules of the CTSA framework. However, full life cycle assessment is not included, and as a consequence the analysis of risks and hazards in both case studies remained somewhat contingent on the analysts' judgment. In the case of surface finishing, for example, the number of chemicals used was taken to be a proxy for the level of hazard. In a full life cycle analysis, the impacts of the chemicals would need to be characterized and related to the volumes of chemicals used. This is a much more data-intensive process, but it is likely to be important because some chemicals are generally benign even at high concentrations, while others can be extremely problematic in minuscule amounts.

Life cycle impact assessment is the preeminent methodology for considering environmental impact and its inclusion would be a powerful contribution to the CTSA model. Because the CTSA methodology predates the widespread adoption of international standards for life cycle assessment, it is unsurprising that life cycle impacts are treated unevenly. A coupled CTSA / LCA would likely have much greater efficacy at predicting and preventing regrettable substitutions than CTSA alone.

Interpretation

CTSA represents an impressive early effort at regularizing alternatives assessment. It excels at producing substantial amounts of information for decision makers to consider. However, it manifests a somewhat ad hoc approach to presentation of results. A CTSA study generates a massive amount of information, but the methodology document is very terse on the subject of how to interpret it. The effect of this oversight is plainly visible in the final sections of both case studies, where it is difficult to draw satisfying conclusions.

The CTSA methodology is essentially sound and can provide abundant insights to a practitioner wishing to perform an alternatives assessment, but it needs to be modernized in order to include recent developments. Life cycle impacts should be treated more robustly, possibly through involvement of ISO14044-style life cycle assessment. Because CTSA modules all produce quantitative data, it may be fruitful to follow a CTSA study with an MCDA exercise (see section 5.3) in an effort to elicit meaningful interpretations of the data.

6.2.3 Danish Ministry of the Environment (MST), 2005-2007

http://www.mst.dk/English/Publications/

The Danish Ministry of the Environment has produced a series of publications which consider the environmental risks and hazards of specific chemicals or chemical classes and

potential alternatives to their use. A number of reports are available on a wide variety of topics, many in English, though only a few can truly be considered alternatives assessments in the spirit of the Green Chemistry Initiative. The organization has never published a methodology or guidance document for alternatives assessment as such. Here we summarize the methodology and outcomes of three separate chemical alternatives assessments, two from 2005 and one from 2007.

Mapping and development of alternatives to chlorinated lubricants in the metal industry – 2005

Environmental Project No. 1039 (Skak et al., 2005)
http://www.mst.dk/Udgivelser/Publications/2005/10/87-7614-807-6.htm

This study considers the use of chlorinated paraffin lubricants, which are used in certain demanding metal-forming applications involving extreme pressure. Because of the high-performance nature of the applications, it has been difficult to identify any alternatives which meet the performance levels of the base case. The purpose of the study was to map out the field of existing alternatives and determine through direct testing which, if any, are potentially viable. The study authors obtained a list of 53 potential alternatives, mostly proprietary, from a variety of manufacturers and suppliers in Denmark, and obtained samples of 19 of these. Through empirical testing they narrowed the field to 4 alternatives which were used in full-scale production trials at a manufacturing facility. All failed. However, the authors mentioned an alternative technology which may have satisfactory performance, though it is proprietary and involves substantial capital costs. The study also included a health and environmental assessment of 15 alternatives and the base case in an effort to develop data for future studies.

This study is notable for its highly technical discussion and investigation. The metalworking processes involved are described in detail. Furthermore, a large number of alternatives was considered, though many were screened out. In the health and environmental assessment, the study was notable in the way it scored the different alternatives. Specifically, it identified a qualitative hazard scale from 1-5 and ranked each chemical component of each alternative on the scale according to its most hazardous quality. Then the score for a given alternative was a sum of the scores of the components, weighted by mass. The result was an evocative visual description of each alternative's environmental and health performance.

The functional unit in this study was defined by the direct needs of the manufacturer, and demonstrated through empirical testing. In this way, the study's structure was similar to the "use-cluster" model used in CTSA (Section 3.1). Because no alternatives were viable, there was no need to choose a preferred alternative; however, the health and environmental scoring discussed above was useful. The study did not consider life cycle effects.

More environmentally friendly alternatives to PFOS-compounds and PFOA – 2005

Environmental Project No. 1013 (Poulsen et al., 2005)
http://www.mst.dk/Udgivelser/Publications/2005/06/87-7614-668-5.htm

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are members of a class of perfluoroalkyl substances, which are short-chain carbon polymers with fluorine instead of hydrogen atoms. These are persistent, bio-accumulative substances which are increasingly detectable in the environment and in humans. The purpose of the study was to evaluate the environmental and health hazards associated with these chemicals and determine whether viable alternatives were available. The study proceeded by identifying the major uses of the substances including technical requirements, assessing the technical performance of the alternatives, evaluating the hazards associated with the chemicals and then of the alternatives. Because of concern from public agencies, many uses of PFOS have already been phased out, but some remain. With the exception of industrial use, many other uses have been or are being phased out. Hazard information was garnered from published literature as well as manufacturers and suppliers, but no laboratory testing was performed directly. Life cycle impacts were not considered.

Alternatives were identified through communication with the industry. There were no identified alternatives to PFOA. Due to the particular performance characteristics of perfluorinated alkyls, most alternatives to PFOS also tend to be highly fluorinated hydrocarbons, for which very little hazard data is available but which can be expected to be substantially similar, and silicones, which are persistent, bio-accumulative and toxic. The study concluded by observing that perfluorinated alkyls are ubiquitous in the environment, and even if PFOS is replaced by shorter molecules, the persistence problem would not be solved.

The functional unit in this study was defined by the needs of manufacturers using PFOS, and remains similar in scope to the "use-cluster" model espoused in CTSA. Here the limited scope of the use-cluster model becomes clear, because the alternatives are found to all present the same essential problem as the base case. It may be that there is no other way to achieve the functionality of PFOS and PFOA, and so eliminating their use may require a radical change in consumers' expectations about the product systems in which they are used.

Health and Environmental Assessment of Alternatives to Deca-BDE in Electrical and Electronic Equipment – 2007

Environmental Project No. 1142 (Stuer-Lauridsen et al., 2007)
http://www.mst.dk/Udgivelser/Publications/2007/01/978-87-7052-351-6.htm

In 2006 the European Commission banned use of all polybrominated diphenyl ethers (PBDE) from being used as flame retardants in electronics; however, they exempted de-

cabromodiphenyl ether (deca-BDE). The MST prepared this study to accompany a legal proceeding in which it sought to overturn the exemption. The agency's goal was to show that alternatives were available which were less hazardous, and so the compound should not have been exempted. Based on a market analysis the agency identified 26 potential substitute chemicals, of which it selected 6 via a screening method for detailed investigation. Because the agency's goal was not to identify an especially safer alternative, only a viable one, their standards for evaluation were the EU regulations regarding permissible and impermissible properties of substances. The extensive EU guidelines on PBT and CMR evaluation served as the basis for their evaluation.

No substances were found which had equivalent technical performance and substantially reduced environmental hazard. All flame retardants were recognized to be persistent in the environment. Deca-BDE is multi-functional, and so it was difficult to identify single alternatives which could substitute for Deca-BDE in all uses. However, one alternative was identified which had equivalent functionality. Although several of the compounds reviewed did have problematic environmental performance, the agency found that none of them were appreciably worse, and some were less hazardous in some areas. The analysis of health hazards relating to the alternatives was motivated by a desire to demonstrate viability with EU regulations, based on existing knowledge of the chemical properties of the alternatives. In that goal, it succeeded; however, it is not clear that any of the alternatives would qualify as safer.

The functional unit in this study was the list of plastic materials in which Deca-BDE could be used as a flame retardant. In each material, the study identified at least one viable alternative. The means for evaluating alternatives was merely whether they were permissible under EU regulations. Life cycle impacts were not considered.

Conclusions

Chemical alternatives analysis (CAA) is the process of developing alternatives to a current use of a toxic chemical and systematically evaluating the alternatives to plan a forward-looking strategy for reducing toxic hazards. CAA begins with the recognition that a chemical in use causes or may potentially cause harm to humans or the natural environment. After this recognition, the CAA process includes three phases: describing the product system and developing alternatives; assessing the relative benefits and drawbacks of the alternatives; and choosing a course of action. By focusing on developing a set of alternative solutions, CAA shifts resources from characterizing "how bad" an existing system is to finding better approaches. While preparing a complete CAA can be an intensive process, the principles underlying CAA are common to all pollution prevention frameworks: an awareness of hazards as well as risks, a life cycle perspective, and an ethos of continuous improvement.

There are two goals inherent in the practice of CAA. Its primary goal is to reduce the level of hazard posed by a given chemical of concern. This goal is accomplished by devising and evaluating possible alternatives. If a possible alternative is found, it must be evaluated in comparison to the existing product system. The secondary goal of CAA is to understand potential regrets and/or unforeseen benefits of each alternative. "Life cycle thinking" provides a basis on which to compare alternatives. By considering the full life cycle of the existing product system and each alternative case, from production of materials to final disposal, an analyst will be able to anticipate the likely impacts of the proposed ideas, leading to knowledge of potential benefits and regrets. The existing product system and alternatives must be studied in the same level of depth so that they can be compared on equal terms. The costs of performing the analysis should be borne by the manufacturers and consumers of products containing harmful or hazardous substances so that the market will provide motivation to phase out those substances and develop innovative alternatives.

To prepare a robust CAA, an analyst must develop a clear picture of an existing product system, describe potential alternatives, both real and speculative, and characterize their strengths and weaknesses. When planning a future course of action, the decision process should be inclusive of stakeholders and consider all relevant criteria. It is important to

consider the full life cycle of a product, not just the aspects of a product over which an analyst has direct control. When a decision is reached, the reasoning behind the decision process should be made transparent. The decision should be revisited regularly as part of a program of ongoing self-assessment. The assessment should continue as long as harmful chemicals are in use.

Understanding the hazard traits of chemicals is a crucial aspect of CAA, but by no means encompasses the entire task. A variety of tools and resources have been developed for characterizing the properties of different chemicals, and public and private organizations have increasingly focused on integrating a diversity of chemical data sets and making them available to the public online. The EPA's ACToR database, the European Union's ESIS, OECD's e-Chem portal, and the online databases under development for California's Green Chemistry Initiative are all examples of this emphasis. In addition to information about chemical traits and properties, CAA also requires knowledge of the chemical's function in the consumer product, the product's supply chain, disposal of both the product and the chemical at end of life, technical performance data and economic cost and benefit information.

Selecting a course of action based on the analysis of possible alternatives is an ultimately subjective process. Clarity and transparency in the process can be found through the use of decision-making tools which make the decision makers' preferences explicit and provide a common framework for comparison. Especially in cases of controversy, having clear documentation of the reasons for a decision can be a powerful aid to finding consensus.

Chemical Alternatives Analysis is a crucial component of the larger coordinated effort of pollution prevention represented by California's Green Chemistry Initiative. The transition toward an economy filled with safer products will be gradual and will require coordination among different industry participants, regulators, and the public. Effective CAA requires the development of infrastructure for companies and independent practitioners to learn from each other, innovation in product design and manufacturing, and inspiration to envision a future free of toxic threats. Through a common commitment among businesses, regulators and consumers to seek safer products and processes, California can reduce the adverse effects of toxic chemicals and usher in a Green Chemistry economy.

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