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Advancing Alternative Analysis: Integration of Decision Science

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Running Head: Integrating Decision Science in Chemical Selection

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Abstract

Background: Decision analysis—a systematic approach to solving complex problems—offers tools and frameworks to support decision making that are increasingly being applied to environmental challenges. Alternatives analysis is a method used in regulation and product design to identify, compare, and evaluate the safety and viability of potential substitutes for hazardous chemicals.

Objectives: Assess whether decision science may assist the alternatives analysis decision maker in comparing alternatives across a range of metrics.

Methods: A workshop was convened that included representatives from government, academia, business, and civil society and included experts in toxicology, decision science, alternatives assessment, engineering, and law and policy. Participants were divided into two groups and prompted with targeted questions. Throughout the workshop, the groups periodically came together in plenary sessions to reflect on other groups' findings

Discussion: We conclude the further incorporation of decision science into alternatives analysis would advance the ability of companies and regulators to select alternatives to harmful ingredients, and would also advance the science of decision analysis.

Conclusions: We advance four recommendations: (1) engaging the systematic development and evaluation of decision approaches and tools; (2) using case studies to advance the integration of decision analysis into alternatives analysis; (3) supporting transdisciplinary research; and (4) supporting education and outreach efforts.

Introduction

Policymakers are faced with choices among alternative courses of action on a regular basis. This is particularly true in the environmental arena. For example, air quality regulators must identify the best available control technologies from a suite of options. In the federal program for remediation of contaminated sites, Government project managers must propose a clean-up method from a set of feasible alternatives based on nine selection criteria (USEPA 1990). Rulemakers in the Occupational Safety and Health Administration (OSHA) compare a variety of engineering controls and work practices in light of technical feasibility, economic impact and risk reduction to establish permissible exposure limits. (Malloy 2014) And now, as we describe below, some agencies must identify safer, viable alternatives to chemicals for consumer and industrial applications. Such evaluation, known as alternatives analysis, requires balancing numerous, often incommensurable, decision criteria and evaluating the trade-offs among those criteria presented by multiple alternatives.

The University of California Sustainable Technology and Policy Program, in partnership with the University of California Center for Environmental Implications of Nanotechnology, hosted a workshop on integrating decision analysis and predictive toxicology into alternatives analysis (CEIN 2015). The workshop brought together approximately 40 leading decision analysts, toxicologists, law and policy experts and engineers who work in national and state government, academia, the private sector, and civil society for two days of intensive discussions. To provide context for the discussions, the workshop organizers developed a case study regarding the search for alternatives to copper-based marine anti-fouling paint, used to protect the hulls of recreational boats from barnacles, algae, and other marine organisms. Participants received data regarding

the health, environmental, technical and economic performance of a set of alternative paints. (See Supplemental Materials) Throughout the workshop the groups periodically came together in plenary sessions to reflect on other groups' findings. This article focuses upon workshop discussion and conclusions regarding decision-making.

We first review regulatory decision making generally, and provide background on selection of safer alternatives to hazardous chemicals using alternatives analysis (AA) also called alternatives assessment. We then summarize relevant decision-making approaches and associated methods and tools that could be applied to AA. The next section outlines some of the challenges associated with decision-making in AA and the role that various decision approaches could play in resolving them. After setting out four principles for integrating decision analysis into AA, we advance four recommendations for driving integration forward.

Regulatory Decision Making and Selection of Safer Alternatives

The consequences of regulatory decisions can have broad implications in areas such as human health or the environment. Yet within the regulatory context, these complex decision tasks are traditionally performed using an *ad hoc* approach, i.e., without the aid of formal decision analysis methods or tools (Eason *et al.* 2011). As we discuss later, such ad hoc approaches raise serious concerns regarding the consistency of outcomes across different cases; the transparency, predictability and objectivity of the decision-making process; and human cognitive capacity in managing and synthesizing diverse, rich streams of information. Identifying a systematic framework for making effective, transparent and objective decisions within the dynamic and complex regulatory milieu can significantly mitigate those concerns. (NAS 2005). In its 2005

report, the National Academy of Sciences called for a program of research in environmental decision-making focused on:

[I]mproving the analytical tools and analytic-deliberative processes necessary for good environmental decision making. It would include three components: developing criteria of decision quality; developing and testing formal tools for structuring decision processes; and creating effective processes, often termed analytic-deliberative, in which a broad range of participants take important roles in environmental decisions, including framing and interpreting scientific analyses (NAS 2005).

Since that call, significant research has been conducted regarding decision-making relating to environmental issues, particularly in the context of natural resource management, optimization of water and coastal resources, and remediation of contaminated sites (Gregory et al. 2012; Huang et al. 2011; Yatsalo et al. 2007). This work has begun the process of evaluating the application of formal decision approaches to environmental decision-making, but numerous challenges remain, particularly with respect to the regulatory context. In fact, very few studies have focused on the application of decision-making tools and processes in the context of formal regulatory programs, taking into account the legal, practical and resource constraints present in such settings (Malloy et al. 2013; Parnell, et al. 2001). We focus upon the use of decision analysis in the context of environmental chemicals.

The challenge of making choices among alternatives is central in an emerging approach to chemical policy, which turns from conventional risk management to embrace “prevention-based” approaches to regulating chemicals. Conventional risk management essentially focuses upon limiting exposure to a hazardous chemical to an acceptable level through engineering and administrative controls. In contrast, a prevention-based approach instead seeks to minimize the use of toxic chemicals by mandating, directly incentivizing, or encouraging the adoption of viable safer alternative chemicals or processes (Malloy 2014). Thus under a prevention-based approach, the regulatory agency would encourage or even mandate use of what it views as an inherently safer process using a viable alternative plating technique. Adopting a prevention-based approach, however, presents its own challenging choice: identifying a safer, viable alternative. Effective prevention-based regulation requires a regulatory AA methodology for comparing and evaluating the regulated chemical or process and its alternatives across a range of relevant criteria.

AA is a scientific method for identifying, comparing and evaluating competing courses of action. In the case of chemical regulation, it is used to determine the relative safety and viability of potential substitutes for existing products or processes that use hazardous chemicals (NAS 2014; Malloy et al. 2013). For example, a business manufacturing nail polish containing a resin made using formaldehyde would compare its product to alternative formulations using other resins. Alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, and changes to component/product design (Sinsheimer et al. 2007). The methodology compares the alternatives to the regulated product and to one another across a variety of attributes, typically including public health impacts, environmental effects, and

technical performance, as well as economic impacts on the manufacturer and the consumer. It identifies trade-offs between the alternatives and evaluates the relative overall performance of the original product and its alternatives.

In the regulatory setting, multiple parties may be involved to varying degrees in the generation of an AA. Typically the regulated firm is required to perform the AA in the first instance, as in the California Safer Consumer Products program and the REACH authorization process (DTSC 2013; European Parliament and Council 2006). The AA, which may be done within the firm or by an outside consultant retained by the firm, is generally performed by an interdisciplinary team of experts (hereinafter collectively referred to as the “analyst.”) (DTSC 2013) The firm submits the AA to the regulatory agency for review. The regulatory agency will often propose a final decision regarding whether a viable, safer alternative exists and the appropriate regulatory action to take. (DTSC 2013; European Parliament and Council 2006). Possible regulatory actions include a ban on the existing product, adoption of an alternative, product labeling, use restrictions, or end-of-life management. Stakeholders such as other government agencies, environmental groups, trade associations and the general public may provide comments on the AA and regulatory response. Ultimately the agency retains the authority to require revisions to the analysis, and also has the final say over the regulatory response (Malloy 2014).

Development of effective regulatory AA methods is a pressing and timely public policy issue. Regulators in California, Maine and Washington are implementing new programs that call for manufacturers to identify and evaluate potential safer alternatives to toxic chemicals in products (DTSC 2013; MDE 2012; Washington State 2015). At the federal level, in the last few years the

U.S. Environmental Protection Agency (EPA) began to use AA as part of “chemical action plans” in its chemical management program (Lavoie et al. 2010). In the European Union, the REACH program imposes AA obligations upon manufacturers seeking authorization for continued use of certain substances of very high concern (European Parliament and Council 2006.) The stakes in developing effective approaches to regulatory AA are high. A flawed AA methodology can inhibit the identification and adoption of safer alternatives, or can support selection of an undesirable alternative (often termed “regrettable substitution.”). An example of the former is the Environmental Protection Agency’s attempt in the late 1980’s to ban asbestos, which was rejected by federal court which concluded, among other things, that the AA method used by the agency did not adequately evaluate the feasibility and safety of the alternatives (Corrosion Proof Fittings 1991 Regrettable substitution is illustrated by the case of anti-fouling paints used to combat the buildup of bacteria, algae and invertebrates such as barnacles on the hulls of recreational boats. As countries across the world banned the highly toxic tributyltin in antifouling paints in the late 1980’s, manufacturers turned to copper as an active ingredient (Dafforn, *et al.*, 2011.) The cycle is now repeating it as regulatory agencies began efforts to phase out copper-based antifouling paint due to its adverse impacts on the marine environment (Carson, *et al.*, 2009.)

AA frameworks and methods abound, yet few directly address how decision-makers should select or rank the alternatives. As the 2014 National Academy of Sciences report on AA observed, “[m]any frameworks . . . do not consider the decision-making process or decision rules used for resolving trade-offs among different categories of toxicity and other factors (e.g., social impact), or the values that underlie such trade-offs.” (NAS 2014). A recent review of 20 AA

frameworks and guides likewise identified methodological gaps regarding the use of explicit decision frameworks and the incorporation of decision-maker values (Jacobs et al. 2015). The lack of attention to the decision-making process is particularly problematic in regulatory AA, in which the regulated entity, the government agency and stakeholders face significant challenges related to the complexity of the decisions, uncertainty of data, difficulty in identifying alternatives, and incorporation of decision-maker values. We discuss these challenges in detail below.

A variety of decision analysis tools and approaches can assist the policy-makers, product and process designers, and other stakeholders who face the challenging decision environment presented by AA. For these purposes, decision analysis is “a systematic approach to evaluating complex problems and enhancing the quality of decisions.” (Eason et al. 2011). While formal decision analysis methods and tools suitable for such situations are well developed (Linkov and Moberg 2012), for reasons discussed below they are rarely applied in existing AA practice. The range of decision analysis methods and tools is quite broad, requiring development of principles for selecting and implementing the most appropriate ones for the varied regulatory and private settings. Following an overview of the architecture of decision-making in AA, we examine how various formal and informal decision approaches can assist decision-makers in meeting the four challenges identified above. We conclude by offering a set of principles for developing effective AA decision-making approaches and steps for advancing integrating decision analysis into AA practice.

Overview of Decision-Making in Alternatives Analysis

In the case of regulatory AA, the particular decision or decisions to be made will depend to significant degree upon the requirements and resources of the regulatory program in question. For example, the goal may be to identify a single optimal alternative, to rank the entire set of alternatives, or to simply differentiate between acceptable and unacceptable alternatives (Linkov et al. 2006). As a general matter, however, the architecture of decision-making is shaped by two factors: the decision framework adopted and the decision tools or methods used. For our purposes the term decision framework means the overall structure or order of the decision-making, consisting of particular steps in a certain order. Decision tools or methods are defined below.

Decision Frameworks. Existing AA approaches that explicitly address decision-making use any of three general decision frameworks: sequential, simultaneous, and mixed (see Figure 1). The sequential framework includes a set of attributes, such as human health, environmental impacts, economic feasibility, and technical feasibility, which are addressed in succession. The first attribute addressed is often human health or technical feasibility, as it is assumed that any alternative that does not meet minimum performance requirements should not proceed with further evaluation. Only the most favorable alternatives proceed to the next step for evaluation, which continues until one or more acceptable alternatives are identified (IC2 2013; Malloy et al. 2013).

The simultaneous framework considers all or a set of the attributes at once, allowing good performance on one attribute to offset less favorable performance on another for a given

alternative. Thus, one alternative's lackluster performance in terms of cost might be offset by its superior technical performance, a concept known as compensation (Giove et al. 2009). This type of trading off is not generally available in the sequential framework across major decision criteria. That said, it is important to note that even within a sequential framework, the simultaneous framework may be lurking where a major decision criterion consists of sub-criteria. For example, in most AA approaches the human health criterion has numerous sub-criteria reflecting various forms of toxicity such as carcinogenicity, acute toxicity, and neurotoxicity. Even within a sequential framework, the decision-maker may consider all those sub-criteria simultaneously when comparing the alternatives with respect to human health (NAS 2014; IC2 2013).

The mixed or hybrid framework, as one might expect, is a combination of the sequential and simultaneous approaches (NAS 2014; IC2 2013; Malloy et al. 2013). So, for example, if technical feasibility is of particular importance to an analyst, she may screen out certain alternatives on that basis, and subsequently apply a simultaneous framework to the remaining alternatives regarding the other decision criteria. A recent study of 20 existing AA approaches observed substantial variance in the framework adopted: no framework (7); mixed (6); simultaneous (4); menu of all three frameworks (2); and sequential (1). (Jacobs et al. 2015).

Decision Methods and Tools. There are a wide range of decision tools and methods, *i.e.*, formal and informal aids, rules and techniques that guide particular steps within a decision framework (NAS 2014; Malloy et al. 2013). These methods and tools range from informal rules of thumb to highly complex, statistically-based methodologies. The various methods and tools

have diverse approaches and distinctive theoretical bases, and address data uncertainty, the relative importance of decision criteria and other issues differently. For example, while some methods quantitatively incorporate the decision-maker's relative preferences regarding the importance of decision criteria (a process sometimes called "weighting") others make no provision for explicit weighting. For our purposes, they can be broken into four general types: 1) narrative, 2) elementary, 3) multi-criteria decision analysis (MCDA) and 4) robust scenario analysis. Each type can be used for various decisions in an AA, such as winnowing down the initial set of potential alternatives or for ranking the alternatives. As Figure 2 illustrates, in the context of a mixed decision framework, two different decision tools/methods could even be used at different decision points within a single AA.

Narrative Approaches. In the narrative approach, also known as the "ad hoc" approach, the decision-maker engages in a holistic, qualitative balancing of the data and associated trade-offs to arrive at a selection (Eason et al. 2011; Linkov et al. 2006). In some cases the analyst may rely upon explicitly stated informal decision principles, or expert judgment to guide the process. No quantitative scores are assigned to alternatives for purposes of the comparison. Likewise no explicit quantitative weighting is used to reflect the relative importance of the decision criteria, although in some instances qualitative weighting may be provided for the analyst by the firm charged with performing the AA. The AA methodology developed by the European Chemical Agency for substances that are subject to authorization under REACH is illustrative (ECHA 2011). Likewise, the AA requirements set out in the regulations for the California Safer Consumer Products program, which mandates that manufacturers complete AAs for certain priority products, adopt the *ad hoc* approach, setting out broad, narrative decision rules without

explicit weighting (DTSC 2013). This approach could be particularly subject to various biases in decision-making, which we address later.

Elementary Approaches. Elementary approaches apply a more systematic overlay to the narrative approach, providing the analyst with specific guidance about how to make a decision. Such approaches provide an observable path for the decision process, but typically do not require sophisticated software or specialized expertise. For example, Hansen and his colleagues developed the NanoRiskCat tool for prioritization of nanomaterials in consumer products (Hansen et al. 2014). The structure may take the form of a decision tree which takes the analyst through an ordered series of questions. Alternatively, it may offer a set of checklists, specific decision rules, or simple algorithms to assist the analyst in framing the issues and guiding the evaluation. Elementary approaches can make use of both quantitative and qualitative data, and may incorporate implicit or explicit weighting of the decision criteria (Linkov et al. 2004).

MCDA Approaches. The MCDA approach couples a narrative evaluation with mathematically-based formal decision analysis tools, such as multi-attribute utility theory (MAUT) and outranking. The output of the selected MCDA analysis is intended as a guide for the decision-maker and a reference for stakeholders affected by or otherwise interested in the decision. MCDA itself consists of a range of different methods and tools, reflecting various theoretical bases and methodological perspectives. Accordingly, those methods and tools tend to assess the data and generate rankings in different ways (Huang et al. 2011). However, they generally share certain common features, which set them apart from the type of informal decision making present in the narrative approach. Each MCDA approach provides a systematic, observable

process for evaluating alternatives in which an alternative's performance across the decision criteria is aggregated to generate a score. Each alternative is then ranked relative to the other alternatives based on its aggregate score. Figure 3 provides an example of the type of ranking generated from a MAUT tool. In most, the individual criteria scores are weighted to reflect the relative importance of the decision criteria and sub-criteria (Kiker et al. 2005; Belton and Stewart 2002).

Some MCDA tools, such as MAUT, are optimization tools that seek to maximize achievement of the decision maker's preferences. These optimization approaches use utility functions, dimensionless scales that range from 0 to 1, to convert the measured performance of an alternative for a given decision criterion to a score between 0 and 1 (Malloy et al. 2013). In contrast, outranking methods do not create utility functions or seek optimal alternatives. Instead outranking methods seek the alternative that outranks other alternatives in terms of overall performance, also known as the dominant alternative (Belton and Stewart 2002). The diverse MCDA tools use various approaches to deal with uncertainty regarding the performance of alternatives and the relative importance to be placed on respective attributes. Some such as MAUT use point values for performance and weighting, and rely upon sensitivity analysis to evaluate the impact of uncertainty (Malloy et al. 2013). Sensitivity analysis evaluates how different values of uncertain attributes or weights would impact the ranking of the alternatives. Others such as stochastic multi-criteria acceptability analysis (SMAA) represent performance information and relative weights as probability distributions (Lahdelma and Salminen 2010). Still others, such as Multi-Criteria Mapping, rely on a part quantitative, part qualitative approach in which the analyst facilitates structured evaluation of alternatives by the ultimate decision-

maker, eliciting judgments from the decision-maker regarding the respective alternatives' performance on relevant attributes and the relative importance of those attributes. The analyst then generates a ranking based upon that input. (SPRU 2004, Hansen 2010). MCDA has been used, though not extensively, in the related field of life-cycle assessment (LCA) (Prado et al. 2012). For example, Wender and his colleagues integrated LCA with MCDA methods to compare existing and emerging photovoltaic technologies. (Wender et al. 2015).

Robust Scenario Approaches. Robust scenario analysis is particularly useful where a decision-maker faces deep uncertainty, meaning situations in which the decision-makers do not know or cannot agree upon the likely performance of one or more alternatives on important criteria (Lempert and Collins 2007). Robust scenario analysis uses large ensembles of scenarios to visualize all plausible, relevant futures for each alternative. With this range of potential futures in mind, it helps decision-makers to compare the alternatives in search of the most robust alternative. A robust alternative is one that performs well across a wide range of plausible scenarios even though it may not be optimal or dominant in any particular one (Kalra et al. 2014).

Robust scenario decision making consists of four iterative steps. First, the decision makers define the decision context, identifying goals, uncertainties and potential alternatives under consideration. Second, modelers generate ensembles of hundreds, thousands or even more scenarios, each reflecting an outcome flowing from different plausible assumptions about how each alternative may perform. Third, quantitative analysis and visualization software is used to explore the benefits and drawbacks of the alternatives across the range of scenarios. Finally,

trade-off analysis (i.e., comparative assessment of the relative pro's and con's of the alternatives) is used to evaluate the alternatives and identify a robust strategy (Lempert et al. 2013).

Decision-Making Challenges Presented by Alternatives Analysis

Like many decisions involving multiple criteria, identifying a safer viable alternative or set of alternatives is often difficult. Finding potential alternatives, collecting information about their performance, and evaluating the trade-offs that each alternative poses, all are laden with problems. Those difficulties are aggravated in the regulatory setting because of additional constraints associated with that regulatory setting, such as the need for accountability, transparency and consistency across similar cases (Malloy et al. 2015). In this review we focus on four challenges recognized in the decision analysis field of particular importance to regulatory AA:

- dealing with large numbers of attributes,
- uncertainty in performance data,
- poorly understood option space, and
- incorporating decision-maker values (sometimes called weighting of attributes.)

Large Number of Attributes. In its essential form AA focuses upon human health, environmental impacts, technical performance and economic impact. But in fact AA involves many more than four attributes. Each of the four major attributes, and particularly human health, includes numerous sub-attributes, many more that any human can process without some form of heuristic or computational aid. Take the case of California Safer Consumer Products regulations, which require that an AA consider all relevant “hazard traits” (DTSC 2013). Hazard traits are

“properties of chemicals that fall into broad categories of toxicological, environmental, exposure potential and physical hazards that may contribute to adverse effects. . .” (DTSC 2013). For human health alone, the California regulations identify twenty potentially relevant hazard traits (DTSC 2013). EPA likewise considers a total of twelve hazard endpoints in assessing impacts to human health in its alternatives assessment guidance (EPA 2011).

Large numbers of attributes raise two types of difficulties. First, as the number of attributes rise, data collection regarding the performance of the baseline product and its alternatives becomes increasingly difficult, time-consuming and expensive. Because not all attributes listed in regulations or guidance documents will be salient or impactful in every case, decision-making approaches that judiciously sift out irrelevant or less important attributes are desirable. Second, given humans’ cognitive limitations, larger numbers of relevant attributes complicate the often inevitable trade-off analysis that is needed in AA. Consider the example of two alternative solders, one of which performs best in terms of low carcinogenicity, neurotoxicity, acute aquatic toxicity, and wettability (a very desirable feature for solders) but not so well with respect to endocrine disruption, respiratory toxicity, chronic aquatic toxicity, and tensile strength (another advantageous feature for solders). Suppose the second alternative presents the opposite profile. Now add dozens of other attributes relating to human health and safety, environmental impacts, and technical and economic performance to the mix. Even in the relatively simple case of one baseline product and two potential alternatives, evaluating and resolving the trade-offs can be treacherous. In assessing the alternatives, decision-makers must determine whether and how to compensate for poor performance on some attributes with superior performance on other attributes. Likewise, the nature and scale of the performance data for the attributes varies wildly;

using fundamentally different metrics for diverse attributes generates a mixture of quantitative and qualitative information.

Decision frameworks and methods should provide principled approaches to integrating or normalizing such information to support trade-off analysis. Elementary approaches often use ordinal measures of performance to normalize diverse types of data. For example, the EPA AA methodology under the Design for the Environment program characterizes performance on a variety of human health and environmental attributes “low” “medium,” or high” (EPA 2011). The increased tractability comes with some decrease in precision, potentially obscuring meaningful differences in performance or exaggerating differences at the margins. As the number of relevant attributes rises, it becomes more difficult to rely upon narrative and elementary approaches to manage the diverse types of data and evaluate trade-offs presented by the alternatives. MCDA approaches are well suited for handling larger numbers of attributes and diverse forms of data. (Kiker et al. 2005). In an AA case study using an MCDA method to evaluate alternatives to lead-based solder, researchers used an internal normalization approach to convert an alternative’s scores on each criterion to dimensionless units ranging from 0 to 1, and then applied an optimization algorithm to trade-offs across more than fifty attributes (Malloy et al. 2013).

Uncertain Data Regarding Attributes. Uncertainty is not unique to AA; it presents challenges in conventional risk assessment and in many environmental decision-making situations. However, the diversity and number of the relevant data streams and potential trade-offs faced in AA exacerbate the problem of uncertainty. In thinking through uncertainty in this context, three

considerations stand out to us: defining it, responding to it methodologically, and communicating about it to stakeholders.

The meaning of the term “uncertainty” is itself uncertain; definitions abound (NAS 2009; Ascough et al. 2008). For our purposes, uncertainty includes a complete or partial lack of information, or the existence of conflicting information or variability, regarding an alternative’s performance on one or more attributes, such as health effects, potential exposure, or economic impact (NAS 2009). It includes “data gaps” resulting from a lack of experimental studies, measurements or other empirical observations, along with situations in which available studies or modeling provide a range of differing data for the same attribute (NAS 2014; Ascough et al. 2008). It also includes limitations inherent in data generation and modeling such as measurement error and use of modeling assumptions, as well as naturally occurring variability due to heterogeneity or diversity in the relevant populations, materials or systems. Uncertainty regarding the strength of the decision maker’s preferences, also known as value uncertainty, is discussed below.

There are a variety of methodological approaches for dealing with uncertainty. Some approaches (typically within narrative or elementary approaches) simply call for identification and discussion of missing data, or use simple heuristics to deal with uncertainties, for example by assuming a worst-case performance for that attribute (DTSC 2013; Rossi et al. 2006). Others rely upon expert judgment (often in the form of expert elicitation) to fill data gaps (Rossi et al. 2012). While MCDA approaches likewise can make use of simple heuristics and expert estimations, they also provide a variety of more sophisticated mechanisms for dealing with

uncertainty (Malloy et al. 2013; Hyde et al. 2003). Simple forms of sensitivity analysis in which single input values are modified to observe the effect on the MCDA results are also often used at the conclusion of the decision analysis process—the lead-based solder study used this approach to assess the robustness of its outcomes—although this type of *ad hoc* analysis has significant limitations (Malloy et al. 2013; Hyde et al. 2003).

Diverse MCDA methods also offer a variety of quantitative probabilistic approaches relying upon such tools as Monte Carlo analysis, fuzzy sets, and Bayesian networks to investigate the range of outcomes associated with different values for the uncertain attribute (Lahdelma and Salminen 2010). Canis and her colleagues used a stochastic decision-analytic technique to address uncertainty in an evaluation of four different synthesis processes for carbon nanotubes (arc, high pressure carbon monoxide, chemical vapor deposition, and laser) across five performance criteria. Rather than generating an ordered ranking of the alternatives from first to last, the method provided an estimate of the probability that each alternative would occupy each rank (Canis et al. 2010). Robust scenario analysis takes a different tack, using large ensembles of scenarios in an attempt to visualize all plausible, relevant futures for each alternative. With this range of potential futures in mind, it helps decision-makers to compare the alternatives in search of the most robust alternative given the uncertainties (Lempert and Collins 2007).

Choosing among these approaches to uncertainty is not trivial. Studies in the decision analysis literature (and in the context of multi-criteria choices in particular) demonstrate that the approach taken with respect to uncertainty can substantially affect decision outcomes (Hyde et al. 2003; Durbach and Stewart 2011). For example, one heuristic approach—called the “uncertainty

downgrade”—essentially penalizes an alternative with missing data by assuming the worst with respect to the affected attribute. In some cases such a penalty default may encourage proponents of the alternative to generate more complete data, but it also may lead to the selection of less safe but more studied alternatives (NAS 2014).

How the evaluation of uncertainties is presented to the decision-maker can be as important as the substance of the evaluation itself. Decision making methods and tools are of course meant to assist the decision-maker; thus the results of the uncertainty analysis must be salient and comprehensible. In simple cases a completely comprehensive assessment of uncertainty may not be necessary. In complicated situations, however, simply identifying data gaps without providing qualitative or quantitative analysis of the scope or impact of the uncertainty can leave decision-makers adrift. Alternatively, it could leave the door open to strategic assessment of the uncertainties aimed at advancing the interests of the regulated entity rather than achieving the goals of the regulatory program. Providing point estimates for uncertain data can bias decision-making, while presenting ranges of data in probability distributions without supporting analysis designed to facilitate understanding can lead to information overload (Durbach and Stewart 2011). Decision analytical approaches such as MCDA can provide insightful, rigorous treatment of uncertainty, but that rigor comes at some potential cost in terms of resource intensity, complexity and reduced transparency (NAS 2009).

Poorly Understood Option Space. The range of alternatives considered in AA (often referred to as the “option space” in decision analysis and engineering) can be quite wide (Frye-Levine 2012; de Wilde et al. 2002). Alternatives may involve (1) use of “drop-in” chemical or material

substitutes, (2) redesign of the product or process to obviate the need for the chemical of concern, or (3) changes regarding the magnitude or nature of the chemical's use (Sinsheimer et al. 2007). Option generation is a core aspect of decision-making; identifying an overly-narrow set of alternatives undermines the value of the ultimate decision (Del Missier et al. 2015; Adelman et al. 1995). Accordingly existing regulatory programs emphasize the importance of considering a broad range of relevant potential alternatives (DTSC 2013; ECHA 2011).

We highlight three issues that complicate the identification of viable alternatives. For these purposes, viability refers to technical and economic feasibility. First, information regarding the existence and performance of alternatives is often difficult to uncover, particularly when searching for alternatives other than straightforward drop-in chemical replacements. Existing government, academic and private publications do offer general guidance on searching for alternatives (NAS 2014; EPA 2011; IC2 2013; Rossi et al. 2012), and databases and reports provide specific listings of chemical alternatives for limited types of products (EPA SCIL). However, for many other products, information regarding chemical and non-chemical alternatives may not be available to the regulated firm. Rather the information may rest with vendors, manufacturers, consultants or academics outside the regulated entity's normal commercial network.

Second, for any given product or process, alternatives will be at different stages of development, some may be readily-available, mature technologies while others are emerging or in early stages of commercialization. Indeed, selection of a technology through a regulatory alternative analysis can itself accelerate commercialization or market growth of that technology. Because the option

space can be so dynamic, AA frameworks that assume a static set of options may exclude innovative alternatives that could be available in the near term (ECHA 2011). Thus identifying the set of potential alternatives for consideration can itself be a difficult decision made under conditions of uncertainty.

Third, the regulated entity (or rather its managers and staff) may be unable or reluctant to cast a broad net in identifying potential alternatives. Individuals face cognitive and disciplinary limitations that can substantially shape their evaluation of information and decision-making. For example, cognitive biases and mental models that lead us to favor the status quo and to discount the importance of new information are well documented (Samuelson and Zeckhauser 1988), even in business settings with high stakes (Kunreuther et al. 2002); this status quo bias is amplified when executives have longer tenure within their industry (Hambrick *et al.* 1993). These unconscious biases can be mitigated to some degree through training and the use of well-designed decision-making processes and aids. Thaler and Benartzi (2004) demonstrate how changing the default can influence behavior in the context of saving for retirement, while Croskerry (2002) provides an overview of biases that occur in clinical decision making, with strategies of how to avoid them. However, such training, processes and aids are largely ineffective where the decision-maker is acting strategically to limit the set of alternatives so as to circumvent the goals of the regulatory process. Many regulated firms have strong business reasons to resist externally driven alterations to successful products, including costs, disruption and the uncertainty of customer response to the revised product.

Incorporating Decision-Maker Preferences/Weighting of Attributes. By its very nature AA involves the balancing of attributes against one another in evaluating potential alternatives. Take the example of anti-fouling paint for marine applications; one paint may be safer for boatyard workers while another may be more protective of aquatic vegetation. In most multi-criteria decision situations, however, the decision-maker is not equally concerned about all decision attributes. An individual decision-maker may place more importance on whether a given paint kills aquatic vegetation than on whether it contributes to smog formation. Weighting is a significant challenge. In many cases, the individual decision-maker's preferences are not clear, even to that individual. This so-called "value uncertainty" is compounded in situations, such as the regulatory setting, in which many stakeholders (and thus many sets of preferences) are involved (Ascough et al. 2008).

Existing approaches to AA vary significantly in how they address incorporation of preferences/weighting. Narrative approaches typically provide no explicit weighting of the decision attributes, although in some instances qualitative weighting may be provided for the analyst. More often, whether and how to weight the relevant attributes are left to the discretion of the analyst (Jacobs et al. 2015; Linkov et al. 2005). Elementary approaches usually incorporate either implicit or explicit weighting of the decision attributes. For example, decision rules in elementary approaches that eliminate alternatives based on particular attributes by definition place greater weight upon those attributes. Most MCDA approaches confront weighting explicitly, using various methods to derive weights. Generally speaking, there are three methods for eliciting or establishing explicit attribute weights: use of existing generic weights such as the set in the National Institute of Standards and Technology's life cycle

assessment software for building products; calculation of weights using objective criteria such as the distance-to-target method; or elicitation of weights from experts or stakeholders (Hansen 2010; Zhou and Schoenung 2007; Gloria et al. 2007; SPRU 2004; Lippiatt 2002). The robust scenario approach does not attempt to weight attributes. Instead, it generates outcomes reasonably expected from a set of plausible scenarios for each alternative, allowing the decision-maker to select the most robust alternative; *i.e.*, the one offering the best range of outcomes across the scenarios.

Each strategy for addressing value uncertainty raises its own issues. For example, in regulatory programs such as Superfund and the Clean Air Act, which use narrative decision-making, weighting is typically performed on a largely *ad hoc* basis, generally without any direct, systematic discussion of the relative weights to be accorded the relevant decision criteria (USEPA 1994, USEPA 1990). Such *ad hoc* treatment of weighting raises concerns regarding the consistency of outcomes across similar cases. Over time, regulators may develop standard outcomes or rules of thumb, which provide some consistency in outcome, but such conventions and the tacit weighting embedded in them can undermine transparency in decision-making. Moreover, lack of clear guidance regarding the relative weight to be accorded to criteria could allow political or administrative factors to influence the decision. However, incorporation of explicit weighting in regulatory decisions creates complex political and methodological questions beyond dealing with value uncertainty. For example agencies generating explicit weightings would have to deal with potentially inconsistent preferences of the regulated entity, the various stakeholder groups and the public at large. Likewise they must consider whether pragmatic and strategic considerations related to implementation and enforcement of the

program are relevant in establishing weighting (UK Department for Communities and Local Government 2009).

Principles for Developing Effective Alternatives Analysis Decision Making Approaches

The previous section focused upon the ways in which the various decision-making approaches can be used to address the four challenges presented by AA. However integrating such decision-making into AA itself raises thorny questions; for example, which of the decision approaches and tools should be used and in what circumstances. In this section we propose four inter-related principles regarding the application of those approaches and tools in regulatory AA.

Different Decision Points Within Alternatives Analysis May Require Different Decision

Approaches/Tools. In the course of an AA, one must make a series of decisions. These include selecting relevant attributes, identifying potential alternatives, assessing performance regarding attributes concerning human health impacts, ecological and environmental impacts, technical performance, and economic impacts, and ranking or selecting the preferred alternatives.

Different approaches and tools may be best suited for each of these decisions rather than a one-size-fits-all methodology. Consider decisions regarding the relative performance of alternatives on particular attributes. For some attributes such as production costs or technical performance, there may be well-established methods in industry for evaluating relative performance that can be integrated into a broader AA framework. Likewise, GreenScreen® is a hazard assessment tool that is used by a variety of AA frameworks (IC2 2013; Rossi et al. 2012). Yet these individual tools are not designed to assist in the trade-off analysis across all the disparate

attributes; for this task other approaches and tools will be needed. Some researchers also recommend using multiple approaches for the same analysis with the aim of generating more robust analysis to inform the decision-maker (Kiker et al. 2005; Yatsalo et al. 2007).

Decision-Making Approaches/Tools Should Be as Simple as Possible. Not every AA will require sophisticated analysis. In some cases, after careful assessment the analyst may conclude that data are relatively complete and the trade-offs fairly clear. In such cases basic decision approaches and uncomplicated heuristics may be all that are necessary to support a sound decision. Thus a simple case involving a drop-in chemical substitute with substantially better performance across most attributes may not call for sophisticated MCDA approaches. Other situations will present high uncertainty and complex trade-offs, and thus call for more advanced approaches and tools. The evaluation of alternative processes for carbon nanotubes involving substantial uncertainty regarding technical performance and health impacts was more suited for probabilistic MCDA (Canis et al. 2010). Likewise not every regulated business or regulatory agency will have the resources or capacity to use high-level analytical tools. Accordingly, the decision-making approach/tool should be scaled to reflect the capacity of the decision-maker and the task at hand, while seeking to maximize the quality of the ultimate decision. Clearly, if the decision will have a major impact but entity regulated firm is currently not equipped to apply the appropriate sophisticated tools, other entities such as non-governmental organizations, trade associations or regulatory agencies should support that firm with technical advice or resources rather than running the risk of regrettable outcomes.

The Decision-Making Approach and Tools Should Be Crafted to Reflect the Decision Context.

Context matters in structuring decision processes. In particular, it is important to consider who will be performing the analysis and who will be making the decision. As discussed above, when AA is used in a regulatory setting, the regulated business will typically perform the initial alternative analysis and present a decision to the agency for review. These businesses will have a range of capabilities and objectives. Some will engage in a good faith or even fervent effort to seek out safer alternatives. Others will reluctantly do the minimum required, and still others may engage in strategic behavior, appearing to perform a good faith AA but assiduously avoiding changes to their product. The decision-making process should be designed with all of these behaviors in mind. For example, it might include meaningful minimum standards to ensure rigor and consistency in the face of strategic behavior while building in flexibility to foster innovation among those firms more committed to adopting safer alternatives.

Multi-Criteria Decision Analysis Should Support but not Supplant Deliberation. The output of MCDA is meant to inform rather than replace deliberation, defined for these purposes as the process for communication and consideration of issues in which participants “discuss, ponder, exchange observations and views, reflect upon information and judgments concerning matters of mutual interest and attempt to persuade each other” (NAS 1996). MCDA provides analytical results that systematically evaluate the trade-offs between alternatives, allowing those engaged in deliberation to consider how their preferences and the alternatives’ respective performance on different attributes affect the decision (Perez 2010). It augments professional, political and personal judgment as a guide and a reference point for stakeholders affected by or otherwise interested in the decision. Yet the output of many MCDA tools can appear conclusive, setting

out quantified rankings and groupings of alternatives and striking visualizations. Care must be taken to ensure that MCDA does not supplant or distort the deliberative process, and that decision-makers and stakeholders understand the embedded assumptions in the MCDA tool used as well as the tool's limitations. For example, Multi-Criteria Mapping methods specifically attempt to facilitate such deliberation through an iterative, facilitated process involving a series of interviews with identified stakeholders. (SPRU 2004; Hansen 2010). Moreover, while MCDA tools summarize the performance of alternatives under clearly defined metrics and preferences, they do not define standards for determining when a difference between performance of alternatives is sufficient to justify making a change. Consider a case in which a manufacturer finds an alternative that exhibits lower aquatic toxicity by an order of magnitude, but does somewhat worse in terms of technical performance. Without explicit input regarding the preferences of the decision-maker, the MCDA tool cannot answer the question of whether the distinction is sufficiently large to justify product redesign. The decision maker ultimately must determine whether the differences between the incumbent and an alternative are significant enough to justify a move to the alternative.

With these challenges and principles in mind, we now turn to the question of how decision analysis and related disciplines can be best incorporated into the developing field of AA.

Next Steps: Advancing Integration of Alternatives Analysis and Decision Analysis

Decision science is a well-developed discipline, offering a variety of tools to assist decision-makers. However, many of those tools are not widely used in the environmental regulatory

setting, much less in the emerging area of AA. The process of integration is complicated by several factors. First, AA is by nature deeply trans-disciplinary, requiring extensive cross-discipline interaction. Second, choosing among the wide range of available approaches and tools, each with its own benefits and limitations, can be daunting to regulators, businesses and other stakeholders. Moreover, many of the tools require significant expertise in decision analysis and are not within the existing capacities of entities engaged in AA. Third, given the limited experience with formal decision tools in AA (and environmental regulation more generally), there is skepticism among some regarding the value added by the use of such tools. Nonetheless we see value in exploring the integration of decision analysis and its tools into AA, and provide four recommendations to advance this integration.

Recommendation 1: Engage in Systematic Development, Assessment and Evaluation of Decision Approaches and Tools. Although there is a rich literature in decision science concerning the development and evaluation of various decision tools, there has been relatively little research focused on applications in the context of AA in particular or in regulatory settings more broadly. While recent studies of decision-making in AA provide some insights, they ultimately call for further attention to the question of how decision tools can be integrated (NAS 2014; Jacobs et al. 2015). Such efforts may include, among other things:

- Developing or adapting user-friendly decision tools specifically for use in AA taking into account the capacities and resources of the likely users and the particular decision task at hand,

- Analyzing how existing and emerging decision approaches and tools address the four decision challenges of dealing with large numbers of attributes, uncertainty in performance data, poorly understood option space, and weighting of attributes,
- Evaluating the extent to which such approaches and tools are worthwhile and amenable to use in a regulatory setting by agencies, businesses and other stakeholders,
- Considering how to better bridge the gap between analysis (whether human health or environmental, engineering, economic or other forms) and deliberation, with particular focus on the potential role of decision analysis and tools, and
- Articulating objective technical and normative standards for selecting decision approaches and tools for particular uses in AA.

The results of this effort could be guidance for selecting and using a decision approach, or even a multi-tiered tool that offers increasing levels of sophistication depending on the needs of the user. The experience gained over the years with implementation of LCA could be useful here. For instance, the development of methods such as top-down and streamlined LCA has emerged in response to the recognition that many entities do not have the capacity (or the need) to conduct a full-blown process-based LCA, and standards such as the ISO 14040 series have emerged for third-party verification of LCA studies.

Recommendation 2: Use Case Studies to Advance the Integration of Decision analysis into AA. Systematic case studies offer the opportunity to answer specific questions about how to integrate decision analysis into AA, and demonstrate the potential value and limitations of different decision tools in AA to stakeholders. Case studies could also build upon and test

outcomes from activities discussed above in Recommendation 1. For example, a case study may apply different decision tools to the same data set so as to evaluate differences in the performance of the respective tools with respect to previously developed technical and normative standards. To ensure real world salience, the case studies should be based upon actual commercial products and processes of interest to regulators, businesses and other stakeholders. Currently relevant case study topics that could be used to examine one or more of the decision challenges discussed above included marine anti-fouling paint, chemicals used in fracking, flame retardant alternatives, carbon nanotubes, and bisphenol A alternatives.

Recommendation 3: Support Trans-sector and Trans-disciplinary Efforts to Integrate Decision Analysis and Other Relevant Disciplines into Alternatives Analysis. AA brings a range of disciplines to bear in evaluating the relative benefits and drawbacks of a set of potentially safer alternatives, including toxicology, public health, engineering, economics, chemistry, environmental science, decision analysis, computer science, business management and operations, risk communication and law. Existing tools and methods for AA do not integrate these disciplines in a systematic or rigorous way. Advancing AA will require constructing connections across those disciplines. While this paper focuses on decision analysis, engagement with other disciplines will also be needed. Existing initiatives such as the AA Commons, Organization for Economic Cooperation and Development (OECD) Working Group, Health and Environmental Sciences Institute (HESI) Committee and others provide a useful starting point, but more systematic research-focused, broadly trans-disciplinary efforts are also needed (BizNGO 2016, OECD 2016). The AA case studies from Recommendation 2 could promote transdisciplinary efforts by creating a vehicle for practitioners to combine data from different

sectors into a decision model. A research coordination network would provide the necessary vehicle for systematic collaboration across disciplines and public and private entities and institutions.

Recommendation 4: Support Undergraduate, Graduate and Post-Graduate Education and Outreach Efforts Regarding Alternatives Analysis, Including Attention to Decision-Making.

Advancing AA research and application in the mid to long term will require training the next generation of scientists, policy makers and practitioners regarding the scientific and policy aspects of this new field. With very limited exceptions (Schoenung et al. 2009), existing curricula in relevant undergraduate, graduate and professional programs do not cover AA or prevention-based regulation. Curricular development will be particularly challenging for two reasons: the relative emerging nature of AA and the trans-disciplinary nature of the undertaking. Its emerging nature means that there is little in terms of curricular materials to begin with, requiring significant start-up efforts. It also makes the subject matter something of a moving target, as new research and methods become available and regulatory programs develop. In terms of the many disciplines impacting AA and prevention-based policy, effective education will itself have to be transdisciplinary. It will have to reach across disciplines in terms of readings and exercises, and engage students and faculty from those various disciplines.

The societal value of research regarding AA methods depends largely on the extent to which research is accessible to and understood by its end-users—policy-makers at every level, NGOs, and business. Ultimately, adoption of the frameworks, methods and tools developed by researchers also requires acceptance by the public more broadly. This requires systematic

education and outreach; namely non-formal education in structured learning environments such as in-service training and continuing education outside of formal degree programs, and informal or community education facilitating personal and community growth and socio-political engagement (Bell 2009). For some, the education and outreach will be at the conceptual level alone, informing stakeholders about the general scope and nature of AA. For others engaged more deeply in chemicals policy, the education and outreach will focus upon more technical and methodological aspects.

Conclusions

There is immediate demand for robust, effective approaches to regulatory AA to select alternatives to chemicals of concern. Translation of decision analysis tools from use in other areas of environmental decision-making to the chemical regulation sphere could strengthen existing AA approaches, but also presents unique questions and challenges. For instance, AAs must meet evolving regulatory standards, but also be nimble enough for the private sector to employ as a tool during product development. To be useful, different tools may be required, crafted for the particular context. The decision approaches employed should be as simple as possible and are intended to support rather than supplant decision making. Trans-disciplinary work, mainly organized around case studies designed to address specific questions, and increased access to education and training would advance the use of decision analysis to improve AA.

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Figure Legends

Figure 1: Decision Frameworks. Compares the process for decision making under sequential, simultaneous, and mixed frameworks.

Figure 2: Multiple Decision Tool Use in Mixed Decision Framework. Demonstrates one potential scenario for using multiple decision tools in one chemical selection process. (derived from Jacobs, et al. 2015 (used by permission <http://ehp.niehs.nih.gov/open-access/>))

Figure 3: Sample Output from MAUT Decision Tool Comparing Alternatives to Lead Solder. SnPb is a solder alloy composed of 63% Sn/37% Pb; SAC (Water) is a solder alloy composed of 95.5% Sn/3.9% Ag/0.6% Cu; water quenching is used to cool and harden solder; SAC (air) is a solder alloy composed of 95.5% Sn/3.9% Ag/0.6% Cu; air is used to cool and harden solder; SnCu (water) is a solder alloy composed of 99.2% Sn/0.8% Cu; water quenching is used to cool and harden solder; SnCu (air) solder alloy composed of 99.2% Sn/0.8% Cu; air is used to cool and harden solder (from Malloy, et al 2013 (used by permission [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1551-3793/homepage/Permissions.html](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1551-3793/homepage/Permissions.html)))

Figure 1
Decision Frameworks

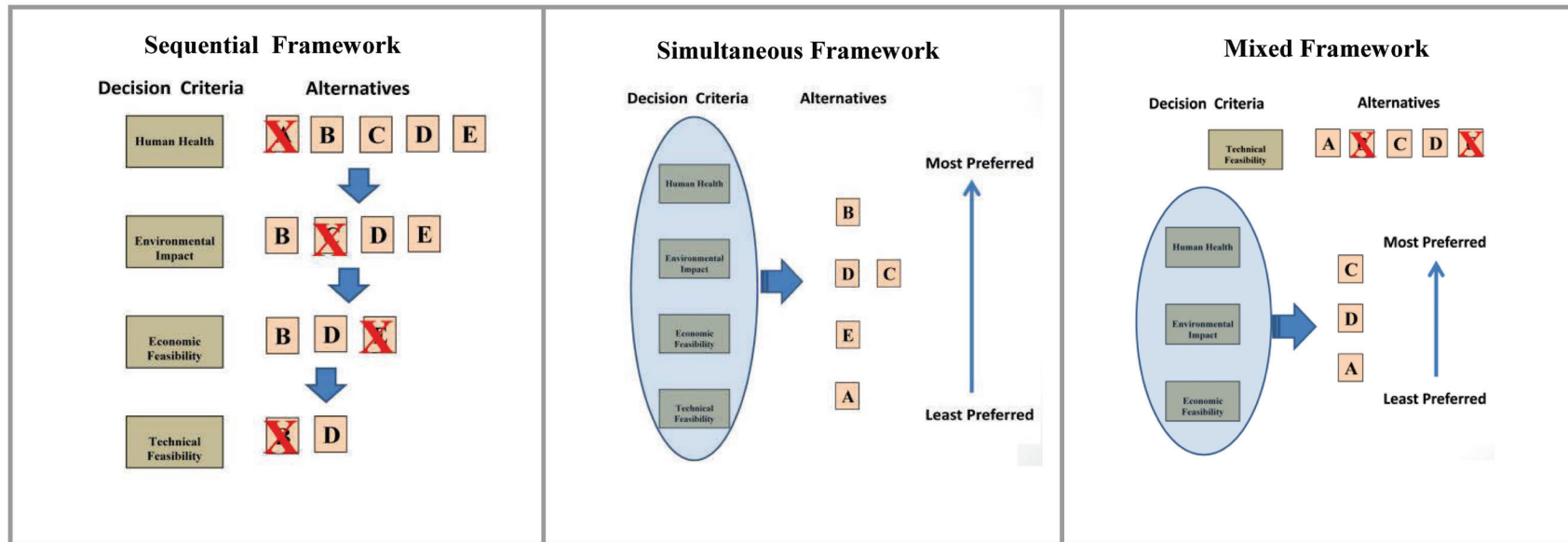


Figure 2
 Multiple Decision Tool Use in Mixed Decision Framework

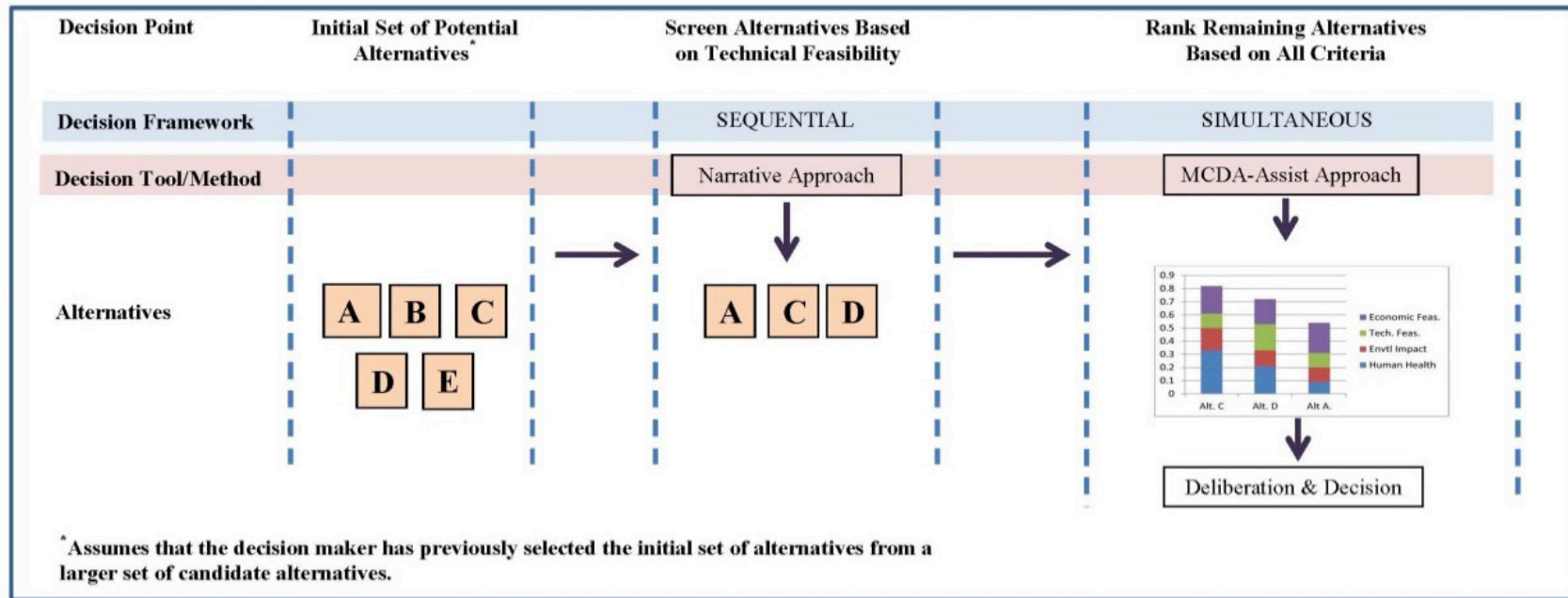


Figure 3

