ELUSIVE CRITICAL ELEMENTS OF TRANSFORMATIVE RISK ASSESSMENT PRACTICE AND

INTERPRETATION: IS ALTERNATIVES ANALYSIS THE NEXT STEP?*

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This paper argues that “game-changing” approaches to risk analysis must focus on “democratizing” risk analysis in the same way that information technologies have democratized access to, and production of, knowledge. This argument is motivated by the author’s reading of Goble and Bier’s analysis, “Risk Assessment Can Be a Game-Changing Information Technology—But Too Often It Isn't” [Risk Analysis (2013) Vol. 33, p. 1942-1951], in which living risk assessments are shown to be “game-changing” in probabilistic risk analysis. In this author’s opinion, Goble and Bier’s article focuses on living risk assessment’s potential for transforming risk analysis from the perspective of risk professionals—yet, the game-changing nature of information technologies has typically achieved a much broader reach. Specifically, information technologies change who has access to, and who can produce, information. From this perspective, the author argues that risk assessment is not a game-changing technology in the same way as the printing press or the Internet because transformative information technologies reduce the cost of production of, and access to, privileged knowledge bases. The author argues that risk analysis does not reduce these costs. The author applies Goble and Bier’s metaphor to the chemical risk analysis context, and in doing so proposes key features that transformative risk analysis technology should possess. The author also discusses the challenges and opportunities facing risk analysis in this context. These key features include: clarity in information structure and problem representation, economical information dissemination, increased transparency to non-specialists, democratized manufacture and transmission of knowledge, and democratic ownership, control, and interpretation of knowledge.

The chemical safety decision-making context illustrates the impact of changing the way information is produced and accessed in the risk context. Ultimately, the author concludes that although new chemical safety regulations do transform access to risk information, they do not transform the costs of producing this information—rather, they change the bearer of these costs. The need for further risk assessment transformation continues to motivate new practical and theoretical developments in risk analysis and management.

KEYWORDS

Risk regulation and policy; technique; alternatives analysis; risk construction
This perspective article has been inspired by the recent paper by Goble and Bier in the November 2013 issue of *Risk Analysis*, “Risk Assessment Can Be a Game-Changing Information Technology—But Too Often It Isn’t,”(1). Goble and Bier promote the idea of using living risk assessment to achieve some of the benefits of information technologies that the risk analysis community has utilized. They identify several features of risk assessment in common with information technology: i.) risk assessments are *repositories of information* and a *medium of its transmission*; ii.) risk assessments are organized with *evaluative structure* that can be used to inform decisions and support value structuring; iii.) risk assessments create the possibility of *asynchronous communication*; iv.) risk assessments *preserve information over time*; v.) risk assessments *serve as a platform for active discussions about risk*; and vi.) risk assessments are distinguished from other decision making tools by their *explicit focus on the uncertainty about future outcomes*. [All emphases are the present author’s.] Their argument culminates in the suggestion that “living risk assessments,” i.e., risk assessments updated in near real-time to support current decisions, should be used more broadly in each of the domains where risk analysis is practiced.

This author’s opinion is that risk assessment, living or otherwise, is presently not a game-changing information technology. While Goble and Bier focus on the practitioner’s perspective, the author argues in this article that the features emphasized by Goble and Bier are not the features of transformative information technologies that make them more democratic and inclusive. Game-changing information technologies not only standardize the representation of knowledge, but they also reduce the cost of access to, and production of, privileged knowledge bases. In short, game-changing information technology gives the broader public both a platform for influencing public discourse, while decentralizing control over the interpretation and use of knowledge.

The demand for incorporating democratic and inclusive features of information technology into risk analysis has empowered some practitioners and stakeholders to advocate for alternatives analysis(2). Many proponents of alternatives analysis argue that current risk assessment practice is too favorable towards dominant political and economic institutions. To a large extent, this critique is situated at the intersection of two risk worldviews: *technique*, the domain of technical specialists, and *narrative*, the approach that potentially can be more amenable to non-specialist
risk construction. For risk assessment to be a game-changing information technology, greater legitimacy needs to be
given to non-specialist risk construction, while democratizing technical risk claims.

The goal of attaining meaningful non-specialist engagement yet ensuring objectively valid risk estimation is much
more simply stated than achieved. While this challenge has been examined by the community in depth (e.g., Douglas
and Wildavsky, 1982(3)), a confluence of changes in academic and professional understanding of risk, combined with
the rapid evolution of the broader public’s understanding of risk, has created unique challenges and opportunities for
the practice of risk analysis that require our urgent attention as a community. The information technology framing is
an attractive approach to engaging these challenges. Consequently, Goble and Bier inspired the present author to join
their discussion by taking a different perspective on the game-changing features that risk assessment must share with
information technology as the interaction between risk assessment professionals and lay persons is also transformed.
The information technology metaphor is particularly attractive to the present author because, as an infrastructure
system, information technology requires adherence to mathematical and bureaucratic standardization that would not
be familiar to lay persons. At the same time, information technologies are accessible to lay persons in ways that do not
require specialized knowledge.

In this paper, the author proposes five features of transformative information technologies and then shows how
failure to perceive these features can lead to public consternation and exacerbation of the adversarial nature of many
important risk analysis contexts. When these features are not present in the risk analysis context, yet are desired by
some stakeholders, opportunities emerge for advances in the way risk analysis is practiced and documented. This
paper then illustrates these emerging opportunities through the specific application domain of alternatives analysis for
safer chemical decision-making (3). This application is selected for its current significance in ongoing regulatory risk
analysis transformations relevant to several important regulations. Thus, the author explores the meaning of
transformative in the alternatives assessment decision context to show how recognition of the need for transformative
potential such as that identified by Goble and Bier is motivating important regulatory opportunities.

2 FEATURES OF TRANSFORMATIVE INFORMATION TECHNOLOGIES
Risk analysis has been developed as a systematic approach to problems of technological uncertainty. Yet, it is not fully warranted to say that risk analysis is transformative in the same way information technologies are. Information technologies have been nothing less than transformative, most importantly in transforming the mechanisms used to create, process, and archive historical and contextual information. These technologies were transformative because they satisfied the following five characteristics: ontological clarity, economical information dissemination, increased transparency, democratized information manufacture and transmission, and increased intellectual agency.

- **Clarity in specification of risk concepts and knowledge base.** Information technologies made advances in the ways information related to extant objects by clarifying categories, symbols, syntax, and other elements. Many information systems capture this idea in the phrase *information ontology*. The definition of information ‘ontology’ was developed by computer scientists to standardize the structure, that is, representation, of information shared between processing agents or applications\(^{(4,5)}\) regardless of their computational, semantic, or other developer-specific commitments. While this definition was developed from the philosophical concept referring to fundamental or ultimate reality\(^{(6)}\), the philosophical definition is not employed in this discussion. Consider, spoken language. Human communication requires that words refer to certain categories (e.g., nouns, verbs), utilize symbols (e.g., syllables, phonetics, etc.), and conform to certain syntax. However, spoken language only applied in the immediate context (i.e., speaker, listener, environment). If the categories referenced did not exist in the immediate environment, the information communicated was not meaningful. In other words, abstract communication was greatly hindered\(^{(7)}\). Written language was an information technology that was transformative because it revolutionized the ontological relationship between language and reality by facilitating abstract reasoning\(^{(7)}\).

- **Economical information dissemination.** Information technologies have generally reduced the cost associated with “manufacturing” and “disseminating” information. This is widely acknowledged, and a classic example is the development of the printing press. The printing press reduced the cost of reproducing manuscripts considerably by providing economic advantages over manual reproduction.
• **Increased transparency.** Information technologies have generally made knowledge bases portable in both encoding (e.g., a computer program for complex automated procedures) and archival (e.g., a chemical risk information clearinghouse database). Here, “knowledge base” can be loosely read as “libraries” or “databases.” By making knowledge bases portable, barriers to access were reduced or removed. The most important barriers to be broken were, of course, economic and class barriers. As these barriers become progressively less effective, information asymmetry is reduced and transparency is increased. In other words, the cost of maintaining “privileged” knowledge bases increases.

• **Democratized information manufacture and transmission.** When combined with increases in transparency, reduction in the cost of information access and dissemination leads to more equitable participation in the information “marketplace”. Because one does not need to be a member of a privileged class to ensure archival and transmission of ideas, access to the information marketplace is liberalized. Democratized information manufacture and consumption is an emergent property of the system-of-systems comprising the Internet.

• **Increased intellectual agency.** Information technologies have transformed the nature of the relationships among actors in the information “marketplace” by providing new mechanisms for attaining influence. Consider Biblical translation and reproduction. If the Bible can be translated and archived in native languages, then widely reproduced using the printing press, many new exegetical meanings can be produced. These new exegetical meanings expand opportunities for attaining influence beyond those opportunities enjoyed by clergy. These exegetical meanings, in turn, provide new “ideascapes” for exploring diverse expressions of religious self-determination and consciousness.

In short, information technologies can be transformative because they can be both democratic and effective. Transformative information technologies have the potential to reduce the barriers to consuming and producing information, liberalize participation in the information landscape, render knowledge portable, and reduce ambiguity in information content. In this sense, they are democratic. They are effective because they may de-centralize the
agency required to achieve generic objectives economically and robustly. Generic objectives are objectives which are true for all stakeholders in the decision context of a specific class of decisions\(^\text{9}\).

In some domains, risk analysis achieves some of these outcomes only with great difficulty, if at all. In fact, it may be misguided to think of risk analysis as an information technology, *per se*. Instead, one should think of risk analysis or risk assessment as a system of information technologies. Under this definition, the system of information technologies known as risk assessment faces significant challenges that must be addressed.

First, the classic article by Kaplan indicates the challenge of ontological clarity within risk analysis\(^\text{10}\): “50% of the problems come from using the same word for different meanings, the other 50% come from using different words for the same meaning.” This notion hardly needs an explanation to this audience. Although risk assessments may “serve as repositories of information, act as a medium of its transmission, create the possibility of asynchronous communication, and preserve information over time”, they are limited in their transformative power. Their ability to support asynchronous decision making is directly constrained by the degree to which the risk assessments were standardized and/or documented. In the absence of adequate standardization or documentation, information is lost due to the conceptual ambiguity perceived by the receiver of the archived risk assessments who is, by definition, divorced from the original context of the analysis. Another ontological factor is the correspondence between what can be called “professional” risk construction and public risk perception and construction\(^\text{11,12}\). Often, the risks that professionals and experts judge to be significant do not employ the same categories used by the affected constituents. This divergence can lead to frustration and acrimony, delaying or preventing meaningful progress towards shared objectives\(^\text{13}\).

Another challenge limiting the transformative potential of risk assessment is the cost of information collection and archival. It is often difficult to economically disseminate risk information, much less collect it and produce it, in order to answer the questions about human or ecological risks attributable to relevant chemical exposure levels. This challenge is widely acknowledged in the risk assessment community and led to the classic classification of risk assessment problems as *trans-scientific*\(^\text{14}\) and *wicked*\(^\text{15}\). The cost of obtaining new information belies an important point that Goble and Bier acknowledge in their analysis: risk assessments in contexts where the cost of updating the
risk knowledge base is prohibitive are “living” in nature, because it is much more cost effective to update the assumptions comprising the context of a risk assessment and re-interpreting the fundamental data than undertaking new mechanistic investigation to re-build the basic toxicologic database. Moreover, the cost of obtaining new information necessarily constrains the population who has ownership of the required basic scientific or technical knowledge. The cost renders this risk information valuable and motivates owners to increase—not remove—barriers to access. This tendency compounds the problem of restricted access, because only “privileged” parties will have the requisite historical or domain knowledge and resources required to interpret the archived analyses and apply them to new scenarios. In other words, risk assessment is a technique of the status quo. [Technique is discussed in a later section of this paper.]

These challenges have led many practitioners and theoreticians to criticize the general lack of transparency in risk assessment. However, this lack of transparency is a necessary artifact of the risk assessment process. Transparency can be generally understood as the ability of a reasonable part of the general public to understand, contribute to, and act on (i.e., operationalize) risk information. It is difficult for a reasonable part of the general public to contribute to risk information due to its prohibitive cost. As a result of the technical nature of risk assessment, a minority of the general public can understand risk information. Therefore, the assumptions and value choices made in the course of a risk assessment may be too arcane for the general public to understand and act upon. Thus transparency—the ability of public stakeholders to identify and understand the assumptions underlying the inferences reported and acted upon in the knowledge base—is often elusive. This difficulty precludes an effective democratization of the risk analysis process, since divisions are often exacerbated by uncertainties that are poorly explained to or understood by non-technical stakeholders. Brickman et al observes the following in the chemical safety context: “massive uncertainties surrounding chemical risk assessment mitigate the power of science as a harmonizing force and open the door to political manipulation of the objectives and results of scientific research.” (p.41) Because one must be a member of the “privileged classes” (i.e., risk analysts, scientists, technologists) in order to understand and produce admissible information to the risk analysis process, only those with effective agency for interpreting and “valuing” risk information belong to the “privileged classes.”
Therefore, the author hopes to renew, not start, a discussion about the transformative possibilities of risk analysis. The author is motivated by engagement with a community of researchers, practitioners, and businesspeople seeking a truly transformative approach to operationalizing risk information in the context of making safer chemical or consumer product formulation and manufacturing decisions. Collectively, the family of techniques used has been called "alternatives assessment," a term coined by O’Brien. Alternatives assessment as an approach has been widely used in several regulatory contexts, but is finding renewed interest as a potentially transformative approach to chemical decision making in the face of incomplete and uncertain information. Thus, the author believes that it is important to further clarify the meaning of transformative, and use the alternatives assessment decision context to show how recognition of the need for transformative potential such as that identified by Goble and Bier is motivating important regulatory opportunities.

3 ALTERNATIVES ANALYSIS: RISK ASSESSMENT IN PUBLIC CROSSHAIRS

Alternatives analysis, also called alternatives assessment, is an emerging, decision analytic technique, for making safer chemical or consumer product composition decisions in the face of deep uncertainty or equivocal hazard evidence without increasing unintended adverse consequences. Alternatives analysis is advocated as a pragmatic interpretation of the precautionary principle, in which the focus of the analysis is on identifying optimal means of accomplishing the function of a product or process instead of identifying the highest level of acceptable harm permissible for a product or process. Although risk analysis is the classic vehicle for implementing the precautionary principle in American regulations, some practitioners of alternatives analysis argue that prevailing risk analysis applications focus on identifying safe levels of exposure in contrast to alternatives analysis’ objective of progressively phasing out the use of hazardous chemicals through replacement with inherently safer ones. In most alternatives analysis methods, the hazards (like neurotoxicity or carcinogenicity) of alternative chemicals or processes are compared and scored. Some approaches use surrogates for exposure in addition to hazard characteristics of alternatives. Examples of alternatives analysis tools and methods include US EPA’s Design for the Environment (DfE), the Lowell Center Framework for Safer Chemicals Selection, CleanGredients®,

While alternatives analysis has been discussed in the literature for some time, more recent case studies and methodological developments have built on the framework presented by O’Brien. O’Brien describes alternatives analysis as a process that culminates in the selection of the best outcome, not simply one that is permitted under currently accepted risk thresholds. In other words, while risk assessment is an input to alternatives analysis, alternatives analysis is more encompassing than risk analysis as a process. The breadth of AA is illustrated in Figure 1.

In the middle of Figure 1 is a range of problem solving situations, from the individual chemical decision to the regulatory and societal context. While both processes involve considerable expert knowledge and individual chemical-level data, alternatives analysis is necessarily broader in its inclusion of social criteria even in the early stages of alternatives assessment. As a result, some practitioners believe that alternatives analysis might lead to innovation at a faster rate and better environmental health outcomes by focusing product formulators and manufacturers on the identification of optimal approaches to avoiding hazardous activities as opposed to designing towards “acceptable” risk levels. Nonetheless, potential misunderstandings of AA have led to perceptions of it as a controversial alternative to current risk analysis practice.

Alternatives analysis is under intense development, as it is the basis of several important emerging statutes, regulations, and policies. Many of these policies are motivated explicitly by the precautionary principle and a new focus on collaborative environmental policy. In Massachusetts, USA, the Toxics Use Reduction Act promotes the use of alternatives analysis as an important tool in implementing this voluntary regulation to reduce public exposure to hazardous compounds. This voluntary regulation engages alternatives analysis through a confidential, voluntary process facilitated through the Toxics Use Reduction Institute. TURA and TURI are part of a unique regulatory mechanism that relies explicitly on collaboration between regulators and policy makers in order to achieve policy goals.

In the European Community, the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation also builds on a participatory mechanism to facilitate the achievement of policy goals.
Moreover, REACH is unique in requiring industrial organizations to demonstrate the safety of a listed product, rather than requiring the regulator to demonstrate its riskiness. Alternatives analysis is incorporated into the REACH process [in the “A” (authorization) stage] as both a means by which actors might demonstrate their products’ safety and also as a means by which regulators might determine whether a chemical can be registered.

While alternatives analysis is implemented on a policy level in the European Community through REACH, there is no equivalent federal legislation in the United States. Several voluntary mechanisms for identifying safer chemical alternatives exist, such as Massachusetts’ TURA, while several state governments are investigating the potential for statutory alternatives analysis. One of these, California, has recently promulgated Assembly Bill 1879 (AB 1879)\(^{(30,38,50)}\), explicitly incorporating alternatives analysis into its requirements. In AB 1879, certain chemicals are listed as “chemicals of concern” by the state. Chemicals of concern are defined as those possessing any of a number of “hazard traits” like potential carcinogenicity or neurotoxicity. Any consumer product sold in California that contains or uses in production a listed chemical must undertake an alternatives analysis in order to demonstrate that no safer alternative can be feasibly implemented to accomplish the same function.

Supporters of these new statutes hope they will be more effective and efficient than the US Toxic Substances Control Act (TSCA). Although TSCA was a landmark regulation when it was originally promulgated, a variety of interacting factors have combined to neutralize the considerable precautionary intent reflected in its original language. These factors might be summarized as\(^{(39-42,51)}\):

1.) Court interpretation of the statute placing burden of proof on EPA for several important procedural requirements, including judicial review requirements for information collection;

2.) Complex procedural requirements intended to ensure dispassionate, comprehensive interpretation of available scientific evidence;

3.) Adversarial relations among stakeholders with access to administrative procedures, interpretations, and courts due to liberal definition of legal standing.
TSCA has been the U.S. statute with the broadest applicability to chemical innovations and with the most influence in chemicals evaluation (except pesticide registration regulations, food and drug regulations, and other influential statutes). Calls for reform of TSCA have widely reflected the fact that ontological clarity is often absent, information collection and dissemination is remarkably costly; the process is obtuse, arcane, and complex; and constituents affected by unwanted exposure to the externalities of chemical innovations feel they have no voice in the process.

Unfortunately, risk analysts, managers, and decision makers may not be able to circumvent such problems in the American context\(^\text{17,18,49,52}\), but the experience with alternatives analysis suggests that citizens are not content to allow the status quo to continue\(^\text{53}\). The design of AB 1879, as well as non-regulatory alternatives analysis tools, directly reflects the failure of risk assessment as traditionally performed to attain the features of a transformative information technology identified and discussed above. As a result, AB 1879 attempts to attain these features, sometimes aggressively:

- **Ontological clarity.** In order to make clear to the public which risks are being addressed, risk categories are derived from existing hazard-based categories used by various North American and European public health regulations and institutions\(^\text{1}\). These categories and their sources are shown in Table I. This type of approach is derived from the 12 principles of green chemistry in which the goal is to avoid hazardous chemicals through the design of new molecules that achieve the same functionality of exiting chemicals, yet pose less intrinsic harm. Some readers will feel that such an approach to risk prioritization does not necessarily improve clarity, and may hide important assumptions and science policy decisions, while not necessarily making the risk categories simpler to understand\(^\text{16}\). This may be true to some extent. The AB 1879

\(^1\) Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986; Annex VI to Regulation (EC) 1272/2008; Article 59 of Regulation (EC) 1907/2006; United States Environmental Protection Agency’s Integrated Risk Information System; 12th Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, National Toxicology Program; Canadian Environmental Protection Act Environmental Registry Domestic Substances List; International Agency for Research on Cancer; Toxic Substances and Disease Registry’s Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System; United States Environmental Protection Agency’s National Waste Minimization Program; Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation; United States Environmental Protection Agency’s Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under the Emergency Planning and Community Right-to-Know Act section 313; and the Washington Administrative Code, title 173, chapter 173-333.
attempts to streamline information collection by using lists of known hazards to “jumpstart” the evaluation process. In this way, the administrative process is being addressed in such a way that action is not unreasonably delayed by the absence of information in a manner that is understandable to most public stakeholders.

- *Economical information dissemination.* Under TSCA, the main costs incurred by the EPA in information collection and dissemination involves establishing the case that an innovation is reasonably expected to be hazardous. The hallmark of alternatives analysis practice in the tradition of O’Brien\(^{(2)}\) is that the goal is not to identify the allowable level of harm, but to identify the lowest level of intrinsic hazard possible. To achieve this goal, alternatives analysis typically reverses the burden of proof in the administrative procedure. Traditionally in the American context, the public administrative agencies must show that a chemical is a probable hazard before further administrative action can be taken. This burden of proof is reversed in AB 1879, in which a two-stage alternatives assessment procedure is established. First, a preliminary alternatives assessment is conducted to establish the need for information collection, then, if necessary, determine whether feasible alternatives must be adopted based on a more detailed analysis of available alternatives in a second phase. This two-stage process is based in large part on exposure considerations, and in principle should be much simpler than the prevailing approach under TSCA.

- *Increased transparency and agency.* To address public transparency and agency, AB 1879 allows great flexibility in the decision trade-off methods that can be used to establish discrimination among alternatives. More importantly, AB 1879 attempts to make the justification for including confidential business information claims in alternatives analysis submissions more stringent. Finally, the California Department for Toxic Substances Control (DTSC) has been actively investigating methods for incorporating public stakeholder values into the trade-off decision context for the purpose of evaluating alternatives analysis submissions\(^{(22,25)}\). In the author’s opinion, these activities reflect a particularly ambitious objective. Finally, the alternatives analysis submissions will be made publicly available by DTSC.
• Democratized information manufacture and transmission. While AB 1879 does not address this dimension in a new or transformative manner, other alternatives analysis tools do facilitate individual interpretation and operationalization of risk data for private decisions. For example, GoodGuide\(^{30,38}\) synthesizes industrial ecology and decision analysis to create integrated product ratings that incorporate performance and health data to enable a consumer to make informed purchasing decisions. In addition, big-box American retailers have used voluntary standards to improve environmental and occupational health impacts throughout their supply chain in response to consumer choices. These approaches move much faster than regulatory procedures, while also enabling consumers to directly act on the risk dimensions that are most meaningful to them.

It is clear that alternatives analysis, from its roots, reflects a deep discontent with the perceived practice of regulatory risk assessment in the American context. The five features identified in this article as transformative features of information technologies are clearly aspirational of goals for AB 1879 and other alternatives analysis-based tools discussed above. First, AB 1879 attains ontological clarity by screening chemicals on the basis of their hazard characteristics, possibly at the expense of the subtlety required of dose-response and exposure evaluation. This is not a transformative innovation \textit{per se}, as many chemical regulations perform some hazard trait screening. However, the transformative potential of this innovation is magnified when combined with a provision in AB 1879 that requires all priority chemicals of concern (CoC) producers or users to submit preliminary alternatives analyses. Compared with TSCA, AB 1879 improves access to these privileged knowledge bases by: i.) reversing the bearer of the costs for producing risk information by reducing procedural requirements to collect hazard and exposure information; and, ii.) making it more difficult to restrict public access to this information through confidential business information (CBI) claims. Second, although it does not increase transparency by enabling non-specialists to contribute to the risk knowledge base, alternatives analysis does increase the potential for more broad risk information consumption. As a result, although non-specialists cannot challenge the validity of the claims, increased public access to the hazard claims by producers and users of priority CoC’s may synergistically improve agency by facilitating the development of third party tools that enable individual consumers to conduct personal risk analyses and make their own choices.
In these ways, AB 1879 is a risk analysis game-changer. AB 1879 is truly designed with the non-specialist citizen, not the specialist or large manufacturer in mind. As such, it achieves some truly transformative characteristics. Nonetheless, alternatives analysis requires novel approaches to benefit-cost analysis, a thorough analysis of its anticipated performance through comparative policy evaluation, and novel practices of decision-analytic evidence synthesis. None of these steps have been taken. Thus, alternatives analysis represents the state of the art in transforming the regulatory relationship between risk analysis and non-specialist general public. As such, it may represent the current limit in our ability to make risk analysis a true “game-changer.”

4 CONCLUSIONS: MOVING FORWARD WITH THE IRGC FRAMEWORK?

The main argument to this point has been that risk assessment, \textit{per se}, is not currently a game changer. The characteristics of truly transformative information technologies are absent: their absence motivates the critiques of those who believe risk assessment practice is favorable to dominant political and economic institutions. This, in turn, has led to the use of alternatives analysis, for example, in American chemicals regulation innovations. This discussion has understood the terms “transformative” or “game-changing” to mean a reconfiguration of the relationship between stakeholders and risk information in a way that broadens access to privileged knowledge bases in the decision context while achieving generic objectives with efficiency and efficacy. The alternatives analysis context suggests that this goal may be too ambitious. At the same time, the International Risk Governance Council (IRGC) White Paper\textsuperscript{(55)} makes some concrete contributions that may inform the evolution of American risk regulation represented by AB 1879 and other alternatives analysis regulations.

For some time, the risk analysis community has been at the intersection between what might be called two risk worldviews: \textit{technique} and \textit{narrative}. The \textit{technique} worldview proceeds from Jacques Ellul’s investigation into the relationship between human civilization and its \textit{techniques}\textsuperscript{(16)}; that is, “\textit{technique} refers to any complex of standardized means for attaining a predetermined result… thus, it converts spontaneous and unreflective behavior into behavior that is deliberate and rationalized.” While the concept is admittedly very difficult to describe concisely, the principal, yet most unfortunate, meaning of \textit{technique} is that modern man searches for the “one right solution” to problems as
dictated by rational or artificial (i.e., objective) methods\(^1\). In other words, this approach to risk suggests that “technical risk estimates represent ‘objective’ probabilities of harm”\(^{(56)}\). In American environmental regulations, technique characterizes the earliest generations of technology-based, point source (or single-source), single-media regulations. Fiorino\(^{(17)}\) calls this generation of environmental policy the “technical learning” paradigm. Problems focused on a single pollutant, associated with a point source, and with readily available technologies for cost effective mitigation; under these circumstances uncertainty and stakeholder preferences play a smaller role compared with the technical construction of risk. On the other hand, this narrative approach has been described by Klinke and Renn\(^{(56)}\) as the constructivist approach. The constructivist risk camp argues, loosely, that it is not possible to attain ‘objective’ risk estimates, and that such a realist view reflects only the views of a scientific and technical elite. Not only is it impossible to validate these views against any ‘objective’ standard, but the science policy choices they must inevitably make in conducting and interpreting the risk assessment cannot be legitimate representations of the values held by the public affected by these risk estimates\(^{(56)}\). The constructivist risk worldview plays an increasingly important role as environmental problems move along the continuum from simple problems requiring only a technical solution, to complex or ambiguous problems requiring the coordination of social, economic, and bureaucratic systems, technical challenges in contaminant remediation, and difficulty identifying a clear scientific construction of risk due to substantial uncertainties in the hazard, dose-response, or exposure data.

Fiorino\(^{(57)}\) discusses two later generations of environmental policy succeeding the simple problems—conceptual learning and social learning. Conceptual learning acknowledges that environmental challenges may involve multiple environmental media, or requiring integration of economic behaviors into the chosen solution. An example of a legislation exhibiting the conceptual learning paradigm is the 1990 Clean Air Act (CAA) Amendments. The 1990 CAA integrates a trading mechanism intended to use market incentives to reduce acid rain and strengthen ozone protections. The CAA acknowledges that these goals are multi-media, and require the control of mobile sources. The CAA pays a heavy price for its innovations; however, it is widely acknowledged that the CAA is the nation’s most complex environmental regulation\(^{(58,59)}\). Consequently, the social learning environmental policy paradigm

\(^1\) The reader is referred to Ellul’s work for a fuller exposition of technique. In the English translation by John Wilkinson, the term technique is left untranslated due to its elusive, yet very rich, meaning.
acknowledges that emerging environmental problems with substantial scientific uncertainties may be too complex to
address using a command-and-control approach to legislation. Instead, social learning involves the implementation of
policies that rely on relationships among stakeholders to achieve environmental objectives at comparatively lower
cost. In the social learning paradigm, the constructivist worldview is paramount. If social learning is required, it is
likely that command-and-control regulation was not feasible due to the costs of risk analysis and the divisive impacts
that scientific uncertainties can have on deliberations between adversarial stakeholders.

The IRGC White Paper also addresses this continuum. The difference between the IRGC model and Fiorino’s
three models—technical, conceptual, and social learning—is that Fiorino is focused on environmental regulation,
while IRGC is focused on a more expansive view of risk governance. IRGC views governance broadly, including
government at all levels, industry, multi-national corporations, non-governmental organizations, and organized or
non-organized citizens. The IRGC continuum has four categories of risk-related problems: simple, complex,
uncertain, and ambiguous. Simple risk problems involve well-known or understood hazards, and can be addressed
using “instrumental” approaches such as benefit cost analysis. Complex risk problems involve decision making
situations where resolving the technical complexities of the problem is more important than resolving the scientific
uncertainties. In other words, complex risk problems are principally characterized by the complexity of the system
they relate to, not by the uncertainty in the relevant scientific knowledge base. On the other hand, risk problems
dominated by unresolved scientific uncertainties fall in the uncertain category. In the complex category, solutions
focus on scientific risk characterization and increasing system robustness. In the uncertain category, the IRGC
recommends that risk management proceeds using hazard characteristics as proxies for risk estimates, while
improving the ability of the system to respond to the unknown. The final category, ambiguous risk problems,
involves risk problems where the values and priorities about competing risks and interests are highly controversial.
Ambiguous risk problems, then, are dominated by conflicting views on what should be done to manage a risk. To use
the IRGC White Paper terms, the technique worldview is the domain of “simple” risk problems, while the
constructivist worldview involves “ambiguous” risk problems. In between, one might place Fiorino’s categories. For
example, the conceptual learning paradigm might map to the IRGC complex and uncertain risk problem categories, while the social learning paradigm could map to the IRGC uncertain and ambiguous categories.

With these categories in mind, one can see more clearly both the innovative and challenging aspects of alternatives analysis based regulations. It is clear that the risk management approaches promulgated in the United States, especially those required by regulatory procedures, have been conceived under the *technique* worldview. The goals of risk assessment, especially in combination with decision analysis, have classically resonated with Ellul’s critique that modern man “converts spontaneous and unreflective behavior into behavior that is deliberate and rationalized.” The American emphasis on cost benefit analysis and procedural complexity was highly successful in addressing the simple,—that is, technical learning,—risk problems. Thus, Ellul’s critique of *technique* seems prescient in light of the characteristics of the American political and economic context. First, the emphasis in American governance on benefit-cost analysis and mandatory enforcement mechanisms make it difficult to address uncertainties in the IRGC’s “uncertain” or “ambiguous” categories. Even the successful CAA illustrates this point, being the most complex US environmental regulation. Alternatives assessment is an innovation in this regard. For example, while benefit-cost analysis is not eliminated from AB 1879, the focus on supporting innovative research and development is intended to promote active replacement of hazardous materials when immediate substitutions to safer chemicals cannot be required. This reflects a classic concern in alternatives analysis that argues that benefit-cost analysis is too often used to justify dangerous activities. Second, the bureaucratic reputation and procedural complexity of American chemicals regulation seem to suggest that there is a “right” risk characterization that is always scientifically achievable. In their classic comparative analysis, Brickman et al. \(^{(17)}\) describe how American regulations have led the American chemicals regulation apparatus to achieve remarkable levels of quantification of chemical hazards and elucidation of quantitative exposure assumptions and estimates. Yet the trans-scientific nature of the problem \(^{(14)}\) ensures that these procedures are only met by unending manipulation and legal challenges due to liberal interpretation of legal standing, adversarial relationships between the executive and legislative branches, and rigorous protection of individual rights and property.
At first glance, one might argue that this risk worldview intersection between *technique* and *constructivist* (or *narrative*) approaches has been present throughout the entire effort to rigorously defend the public against technological risk in the 20th century. Upon further reflection, one must ask why quantification and elucidation of assumptions only multiplied, not diminished, in the face of such challenges. This results stems from the fact that the American risk management and assessment paradigm has been fully captured by *technique*. Alternatives analysis does not solve this problem, *per se*, but it does place the focus on risk management through reduction of intrinsic hazard. Here, one could argue that alternatives analysis attempts to address problems in the uncertain/conceptual learning categories by using hazard characteristics as proxies while hoping to promote development of diverse alternatives to improve the resilience of the economic system to potentially adverse unintended risk consequences. This view follows very closely the guidance in the IRGC framework, but it is unclear how this approach will evolve in the American political and policy context.

Risk assessment as *technique* has been challenged for some time now, as evidenced by writings of many researchers\(^{(60-63)}\). The common thread in these challenges is that the general public cannot participate in the construction of risk *à la technique*, and the representation of their values and perception is not present in such risk constructions. As a result, they do not accept the legitimacy of management decisions made based on the realist perspective. Instead, risk construction should include not only the ‘objective’ scientific evidence and economic theoretical justification, but also the perception of the likelihood and consequences of exposure to technical hazards by the communities to be affected. This leads us to one of the most controversial characteristics of alternatives analysis regulations, and AB 1879 in particular—the confluence of risk analysis and risk management. Alternatives analysis strikes a middle ground between these two goals. Although the focus is on the assessment of alternatives to a particular chemical or product, the AB 1879 statute is sufficiently flexible to allow a diversity of approaches to that assessment. Thus, while there is not necessarily a risk assessment step, risk assessment will certainly be used by some manufacturers in their own evaluation of the alternatives, and justification of the choices available to them. While some stakeholders will not be pleased with the requirement that chemicals of concern be progressively substituted, in the best case scenario the public will feel that their interests have not been subjugated to more powerful stakeholders.
from the beginning. At the same time, alternatives analyses are produced by those most knowledgeable of the
chemical or product and its capabilities—the producer or manufacturer. These analyses are usually submitted to the
relevant regulatory agency and evaluated on a case-by-case basis. While alternatives analysis is game-changing in the
sense that it reduces barriers to information collection, and presumably reduces procedural complexity, it still does
not enable non-specialists to produce their own knowledge and interpretations of the data.

This discussion suggests that alternatives analysis is a special case of a policy emerging from the tension between
technique and constructivist risk worldviews. Alternatives analysis is clearly a game-changer, especially in the
American context. Alternatives analysis is gaining momentum because traditional chemicals risk assessment too often
does not possess the characteristics of transformative information technologies: clear understandable representation
for all involved stakeholders (ontological clarity), economical information dissemination, increased transparency,
democratized information manufacture and transmission, and increased ability by the general public to interpret and
act on risk information (intellectual agency). Although alternatives analysis as implemented in AB 1879 does not
achieve all of these, comparison of a few of its characteristics with the IRGC Risk Governance Framework suggests an
exciting future for evolutionary developments in American chemicals regulation.

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Committee. This research received no financial support. All opinions and errors remain those of the author only.
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64. California Department of Toxic Substances Control. Safer Consumer Products. Division 4.5, Title 22, Chapter 55; 2013 pp. 1–72.
Figure 1. Similarities and contrasts between risk analysis and alternatives analysis over the continuum between individual chemical use/production decisions and societal impacts of those decisions. How do they compare along the range of problem solving situations from individual chemical decisions at the testing and product formulation level to public and ecological health protection or economic competitiveness concerns at a societal level? Risk analysis data are more heavily based on a narrower context at the individual or product formulation level, versus alternatives analysis that more broadly integrates other societal concerns. While both processes involve considerable expert judgment and chemical-level data, alternatives analysis is necessarily broader in its inclusion of social criteria even in the early stages of the alternatives assessment process.
Table I. Priority characteristics and data sources for chemicals listed in the AB 1879 Chemicals of Concern list\(^{(2,64)}\).

<table>
<thead>
<tr>
<th>Priority Characteristics</th>
<th>Sources</th>
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<tbody>
<tr>
<td>i. Carcinogenic (known to be, reasonably anticipated to be, or likely to be, etc.)</td>
<td>i. Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986</td>
</tr>
<tr>
<td>ii. Mutagenic</td>
<td>ii. Categories 1A and 1B in Annex VI to Regulation (EC) 1272/2008</td>
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<tr>
<td>iii. Reproductive or developmental toxicant</td>
<td>iii. Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006</td>
</tr>
<tr>
<td>iv. Endocrine disrupting</td>
<td>iv. United States Environmental Protection Agency’s Integrated Risk Information System</td>
</tr>
<tr>
<td>v. Persistent, bioaccumulative, or toxic (PBAT)</td>
<td>v. 12th Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, National Toxicology Program</td>
</tr>
<tr>
<td>vi. Very Persistent, bioaccumulative, or toxic (vPBAT)</td>
<td>vi. Canadian Environmental Protection Act Environmental Registry Domestic Substances List</td>
</tr>
<tr>
<td>viii. Currently regulated (e.g., USEPA RfD or RfC in IRIS)</td>
<td>viii. International Agency for Research on Cancer</td>
</tr>
<tr>
<td>ix.</td>
<td>ix. Toxic Substances and Disease Registry’s Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System</td>
</tr>
<tr>
<td>x. United States Environmental Protection Agency’s National Waste Minimization</td>
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</table>
xi. Monographs on the Potential Human Reproductive and Developmental Effects, National Toxicology Program, Office of Health Assessment and Translation

xii. United States Environmental Protection Agency’s Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under the Emergency Planning and Community Right-to-Know Act section 313


xiv.