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Editorial

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Editorial

This issue of HERA contains an important perspective article by Dr. Adam Finkel, who writes on the subject of solution-based risk assessment. Dr. Finkel's contributions to the development and practice of risk assessment are both numerous and substantial. We are pleased to bring his latest risk assessment proposal to the attention of our journal's readership. We are equally pleased to publish a set of distinguished commentaries on Dr. Finkel's proposal. The commentators are themselves persons who have made major contributions to the field of risk assessment and associated areas of scientific practice and policy development. The commentaries provide important perspectives on current and future directions of risk assessment practice. Our journal would be pleased to receive comments from our readers on any or all of these important articles. Comments should be presented as concise letters to the editor. We look forward to any and all comments.

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Perspective Article

"Solution-Focused Risk Assessment": A Proposal for the Fusion of Environmental Analysis and Action

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ABSTRACT

For 30 years, more attention and resources have been expended on dissecting problems (risk assessment) than on evaluating actual solutions that reduce risks. The basic dogma holds that risk assessment must precede risk management. But there is an opposite and perhaps better way: the opening question should not be "How bad is the problem?" but "How good are the solutions we might apply to the problem?" Rethinking risk assessment in this context offers three classes of benefits over the status quo. First, it can help break the endless cycle of analysis: when the goal is to know enough to decide, rather than to know everything, natural stopping points emerge. Second, it can lead to more decisions that actually achieve risk reduction, rather than pronouncements about how much risk reduction *would* be optimal. Third, it can highlight ways to resolve multiple risks simultaneously, avoid needless and tragic risk-risk tradeoffs, and involve affected stakeholders in debating what should be done. Arguably, the longer the disembodied analysis of risk information is allowed to proceed, the more likely it is that the "problem" will be defined in a way that blunts the free-wheeling discussion of solutions, to the detriment of human health, the environment, and the economy.

Key Words: risk management, standard-setting, decision theory, public involvement, technology options.

INTRODUCTION

We have steadily allowed the analysis of risks to health, safety, and the environment to drift apart—conceptually, bureaucratically, functionally—from the actions we take (or fail to take) to reduce these risks. It is time to repudiate both of the extremes—headstrong actions uninformed by careful analysis, and endless analysis

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leading only to more understanding rather than to any tangible benefits—in favor of a new paradigm, one in which scientific and economic knowledge is harnessed to identify reliable, creative, and equitable solutions to health, safety, and environmental problems.

This article proposes we use risk assessment as a central part of a fundamentally different way to relate analysis and risk management. This proposal is in some ways complicated and in others deceptively easy and therefore easy to misconstrue, object to for attributes not intended, or misperceive as something we are already doing. I encountered each of these problems as a member of the committee that produced *Science and Decisions: Advancing Risk Assessment* (NRC 2009)—Chapter 8 of that report contains a new decision-making framework with a few elements of what I advocated for, along with various other elements that others proposed. I would characterize the proposal in this article as more ambitious than what our committee reached full consensus on, and therefore more in need of careful appraisal and constructive criticism.

This article introduces a concept I call "solution-focused risk assessment" (SFRA). To oversimplify, I basically suggest that we should think our way from options to decisions—informed by the rigorous analysis of problems—rather than letting the analysis of problems run wild and lead (at best) to knowledge rather than to action. Much of this article will acknowledge but ultimately reject the simplistic objection that "you cannot think about solutions before you fully understand the problem." But SFRA has a larger ambition than changing the sequencing of the contributions of risk managers (and engineers) vis-à-vis risk assessors. By thinking about solutions first, we can open our minds and open up the political/bureaucratic process to *better* solutions than the risk-based paradigm allows. Of course, this means that solutions may emerge that some will attack as too ambitious, but this must be understood as a particularized objection to an output of SFRA, not necessarily as a criticism of the idea itself.

To assert that we need to balance the resources devoted to dissecting problems and the resources devoted to implementing beneficial policies may seem trite, but I argue herein that the steady rise of quantitative risk assessment (QRA) and cost–benefit analysis (CBA)—two developments I enthusiastically welcome—has crowded out improvements in how we solve problems, and in some instances has even begun to lull us into a false sense that we are doing *anything* to improve health and the environment. This was not an inevitable consequence of more rigorous analysis, and it therefore can be reversed without compromising that rigor by one iota. As a former director of the health regulatory programs at the U.S. Occupational Safety and Health Administration (OSHA), I regard the risk-centered path that the U.S. Supreme Court laid out for OSHA and thence the rest of the U.S. regulatory system (Industrial Union Department 1980—the "Benzene" case) as absolutely the right tool for the job—just not necessarily a tool that has been used to its best advantage in the intervening 30 years (Goldstein *et al*. 2010).

In organized attempts to protect public health and the environment, the relationship between analysis and action is driven by the interactions (and non-interactions) between assessors and decision-makers, who jockey both on behalf of their disciplines (science and economics, law and politics, respectively) and as individuals seeking influence. In addition to the amount of effort devoted to either

assessment or management, however, the sequencing and content of the interactions is of paramount importance. This proposal seeks not only to focus relatively more attention on risk management, *but to change the nature of the questions risk assessors are directed to answer.* In a nutshell, this reverses the process first codified in the 1983 "Red Book" (NRC 1983), in which assessors study problems and managers may *then* use this information to develop and choose among alternative control strategies, into one in which a tentative set of alternatives comes first and the analyses explore how these alternative decisions would impel changes in risk (and cost).[1]

Such a reversal would place risk assessors into the same common-sense relationship that experts and other purveyors of information have always had with those who seek their counsel in everyday life. The mundane utterance "I've got a problem . . . " is commonly an overture to " . . . and I don't know what to do about it." Only in the psychiatrist's office, and perhaps in the environmental, health, and safety regulatory agencies, is it instead seen as an overture to " . . . and I don't know how to think about it."

As a risk assessor, I know that the expertise my colleagues bring can help decision-makers think, but as a citizen, I wonder if instead that expertise should help them decide what to do. Somehow, our environmental protection apparatus has evolved to the point where some of our best minds are occupied helping society think about risks, not helping society reduce risks expeditiously and efficiently. Because we have become so comfortable quantifying risks and costs (and have by and large become rather good at this part of it), we often look to "optimize" the variables before we consider the specific options for reaching *any* aspirational goal. In our daily lives, we know that free-form optimization can result in our dreams remaining just dreams. No lonely 20-year-old would sensibly treat the utility function (the more attractive a partner I can find, the happier I will be) and the opposing likelihood function (the more attractive the partner, the less chance I have of attracting him or her) as a constrained-optimization problem whose culmination is a quantification of the ideal prospective partner. Common sense tells us in this case that one needs to meet real people and compare them, not to stay indoors with a calculator.

This proposal is both, and equally, aimed at improving risk management and risk assessment—but rather than adding any major ideas to the litany of admirable technical improvements to risk assessment offered by many others (NRC 1994; Paustenbach 1995; Lutz 2001; Hattis *et al.* 2002) I aspire, in the spirit of taking some of

[1]Much has been written (see especially the entire special issue in August 2003 of *Human and Ecological Risk Assessment*) about whether the current conception of the desired risk assessment/risk management relationship actually originated with the Red Book committee, or arose through extrapolation beyond what the "mis-Read" book actually said. Through discussions with many of the original committee members (and through service on the two National Research Council panels convened circa 1994 and 2006 to re-examine these issues), I have come to believe that the Red Book committee did not oppose the notion of a symbiotic and iterative relationship between risk managers and risk assessors, so long as the functions were kept "conceptually separate." However, by concentrating on the landmark four-step process map for how risk assessment could best be carried out—and by omitting any detail about what kinds of questions assessors should be pursuing—the Red Book did contribute greatly to the impression that risk assessment should "pass the baton" to risk management, rather than vice versa.

the pressure off of analysis (Goldstein 1993), to increase its usefulness, and perhaps selfishly, even to make the assessors' jobs more interesting. *We assessors can answer narrow, obscure, and deflating questions well, but we can also answer broad, momentous, even lofty questions well, if we are empowered (or assert the power) to consider them.* Many other commentators (see especially Table 2 below of this article) have urged broadly that risk assessors and risk managers "break down the firewall" and collaborate more, but this proposal offers a specific vision of collaboration that challenges risk assessors to help ask and help answer risk management questions. In short, this proposal aspires not merely to help us declare more missions accomplished, but to actually accomplish more missions.

SUMMARY OF PROPOSAL

Solution-focused risk assessment, as I define it, *must* change the timing of when risk assessors consider risk management solutions, and *may* change the nature of the solutions considered. Without the "mandatory" process change, there is no SFRA, but it is possible to reject the "optional" rethinking of the kinds of risk management options we are willing to contemplate and still transform the paradigm. Therefore, I will later refer to a more ambitious "SFRA 2.0" when discussing the pros and cons of changing both the "when" and the "what" to a solution-focused approach.

The most basic definition of any form of SFRA is that it occurs when alternative risk management pathways are arrayed before detailed scientific analyses of exposures, potencies and risks begin—in order that these analyses can focus on the risks (and the costs) of specific actions. Shown in Figure 1 are simplified process maps both for the current (traditional) paradigm and for SFRA. Various agencies have added all manner of "bells and whistles" to the 1983 Red Book diagram in which the four steps of risk assessment precede risk management, but Figure 1 remains faithful to much of present-day

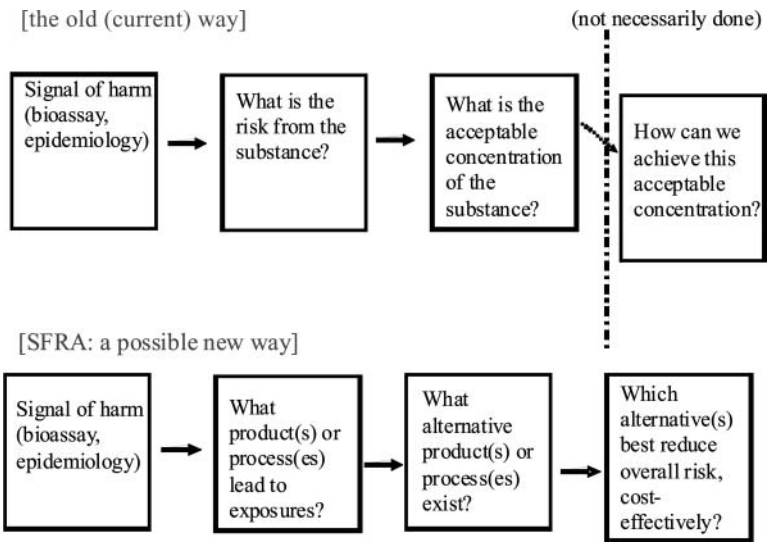

Figure 1. Comparison of the current way with a possible new way.

decision-making. In particular, the U.S. Environmental Protection Agency (USEPA) has come to rely more and more of late on a "damage function approach"—which maps "emissions to concentrations to exposure to effects to benefits." This, however, only adds detail to the same basic logic: risk assessment culminates when it provides a way to convert changes in emissions (or concentrations) to changes in benefits.

Neither in traditional nor solution-focused assessment should (or do) detailed risk assessments snowball on their own absent a "signal of harm" (generally, adverse findings from one or more bioassays, epidemiologic investigations, or observations of adverse ecological change). In either paradigm, reliable conclusions that there is no problem—for example, that exposures are non-existent or negligible, and/or that the signal of harm was a false positive—can and should end the exercise. There may also be situations in which the problems are clearly non-trivial but no conceivable risk-reduction options exist (this may tend to occur, for example, with naturally occurring contaminants ubiquitous in soil or other environmental media); here, too, further efforts to analyze either risks or solutions would be wasteful at present.

However, in all other kinds of cases—where we analyze risks under the reasonable expectation that there exist various optimal, sensible (but sub-optimal), ineffectual, or perverse (net-risk-increasing) ways to reduce them—I assert that there can be enormous differences between the outcomes of an assessment-first process and a solution-focused process.

Consider the likely results of a traditional versus a solution-focused approach applied to the very basic task of controlling a particular substance present in ambient or workplace air. At USEPA, both the National Ambient Air Quality Standards (NAAQS) process for criteria air pollutants and the residual risk process for toxic/carcinogenic air pollutants[2] embody the assessment-first approach: risk assessors work to establish an ambient concentration that either (in the former case) is "requisite to protect the public health ... allowing an ample margin of safety," or that would assure that "the individual most exposed to emissions from a source [of a given substance]" does not face a lifetime excess cancer risk greater than 10^{-6}. At OSHA, risk assessors work to establish an occupational exposure concentration (the Permissible Exposure Limit, or PEL) that comports with the 1980 Supreme Court decision in the *Benzene* case (Industrial Union Department 1980) (*i.e.*, does not reduce lifetime excess fatality risk beyond the boundary of "insignificance," which the Court rather unhelpfully said falls somewhere between 10^{-3} and 10^{-9}), although here an assessment of economic and technological feasibility is often the limiting factor in constraining the PEL[3] (Finkel and Ryan 2007).

But doing the assessment is not at all the same as reducing the risk. Sometimes we *pretend* that the assessment sets the table for the management of risk, when in fact we

[2]I will return to the toxic air pollutants example in the section "Echoes of SFRA in Familiar Places," as I recognize that here the U.S. Congress in the Clean Air Act Amendments of 1990 also established a technology-based process to precede the residual risk phase that USEPA is now undertaking.

[3]Note that because OSHA generally sets one limit for a substance across all industries, there is no attempt to consider whether the PEL requires "best available technology" to achieve—only that in one or more sub-sectors the PEL could be set no lower without going beyond what is economically palatable.

do little or nothing to turn what is *per se* nothing more than a pronouncement—"*if* the concentration of substance X in ambient air falls below the NAAQS, then the ample margin of safety shall have been provided," or "*if* workers breathe substance Y at less than the PEL, then their risk shall be acceptably small"—into actions that can move us to, or closer to, the desired state of affairs.

This grim verdict is not merely a pessimistic appraisal of the vagaries of separating goal-setting from regulatory enforcement. I appreciate that (for example) the U.S. Congress intended the NAAQS process to bifurcate, with a pronouncement about what concentration is desirable at the national level totally separate from the subsequent approval of State Implementation Plans that should specify how each U.S. state will strive to attain the desired concentration. I also appreciate that failure to enforce specific mandates is sometimes the problem, rather than failure to choose them at all. I simply observe that there are some fundamental, although remediable, deficiencies with the very idea of setting risk-based goals:

- We may forget to ever move beyond articulating the goal, toward furthering the goal! I worry that even the use of the term "decision" to announce the culmination of the limit-setting step of processes like the NAAQS and PELs (*e.g.*, USEPA (2008) explained "the Administrator has *decided* to revise the level of the primary 8-hour O3 standard to 0.075 ppm") (emphasis added) puts us on a slope toward believing that intoning a number is in any way tantamount to "deciding" anything.
- *Most "risk-based" goals are in fact exposure-based goals*, with an implicit but perhaps grossly misleading connection equation made between exposure reduction and actual risk reduction. Even if every establishment that had a workplace concentration greater than a new OSHA PEL immediately ended all excursions greater than that concentration, worker risk might actually rise rather than fall, if the compliance behavior entailed substituting a more toxic substance for the regulated one. The growing literature on "risk-risk tradeoffs" (Keeney and von Winterfeldt 1986; Graham and Wiener 1995; Sunstein 1996; Wiener 1998; Rascoff and Revesz 2002) attests to the complexity of risk management and to the ease with which good intentions can produce untoward results.[4]
- Most fundamentally, the ways we ultimately manage risk will likely differ depending on whether we set the goal first and only subsequently think about the best way(s) to achieve it, or instead set our sights immediately upon trying to find the best way(s) to maximize net benefit (or achieve "acceptable risk," or any other endpoint dictated by law or policy). *A major aim of this article is to argue that a "solution focus" will not just produce different results, but it will produce superior results compared with the traditional paradigm.*

[4]In a recent presentation (Finkel 2007), I argued that many of the most publicized "tradeoffs" were in fact either concocted by the regulated industry to deter agency action (and were never plausible responses to the regulation), or should have more properly been interpreted as "wake-up calls" to find cost-effective ways to control both the primary and the offsetting risk. Nevertheless, I believe that many legitimate tradeoffs do exist and should be accounted for in policy (see 'A Specific Example' below).

For all three reasons—the traditional process can end with no risk-reduction actions at all, with actions that increase net risk, or actions that are less efficient than otherwise attainable—a decision process that thinks its way from solutions to problems, rather than from problems to solutions, is well worth adopting. Although I present a detailed case example near the end of this article, consider the stylized general example below as an introduction to a "solution-focused" process:

After 15 years of drafting and redrafting, USEPA synthesizes all the toxicologic and epidemiologic evidence about the cancer and non-cancer effects of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), and recommends an Acceptable Daily Intake (ADI) in pg/kg/day. A U.S. National Academy of Sciences committee then rank-orders various broad anthropogenic sources of TCDD (*e.g.*, coal combustion, pulp and paper effluent) by the fraction of total environmental loading they contribute, and various agencies set priorities among the sources within their purview. Together, their goal is to steadily reduce entry of TCDD into the environment until everyone's uptake falls below the ADI. But suppose instead that early into the scientific assessment phase, USEPA and the U.S. Food and Drug Administration (FDA) collaborated to examine the various products available to filter coffee and to brew hot tea in residential and commercial use—the most common of which rely on chlorine-bleached paper and which add trace amounts of TCDD to the diets of tens of millions of Americans. Other means exist to produce white coffee filters, unbleached paper filters or metal mesh filters could be produced, and some methods do not rely on mechanical filtration at all. Each alternative has implications for the price, taste, and risk level of the finished beverage, and these factors can be evaluated comparatively in a multi-attribute decision-making framework; the results could drive policies ranging from information disclosure to tax incentives to subsidized research and development to outright bans on products deemed needlessly risky. The steps taken would not "solve the TCDD problem," but might solve the portion of it attributable to these particular sources.

So with reference to Figure 1, the key step that makes a decision process "solution-focused" is the second one in both the upper and lower process diagrams, which is really the first step in the process where risk assessment and/or risk management begin. *SFRA requires an initial brief moratorium on conducting free-form exposure and dose–response assessment until the risk managers and assessors convene and discuss the following sorts of questions:* What are the sources of this potential harm? (How) can the social purposes that the sources serve be fulfilled with less risk to human health or the environment? And how can we quantify the implications of each possible risk-reducing intervention on risk, cost, equity, offsetting risk, and any other factor we should consider before choosing whether and how to intervene? The same dose–response, exposure, cost, and other information will likely be needed under both paradigms, but in the solution-focused process, that information will help discriminate among feasible alternatives, rather than be packaged first and only later re-opened in the (vain?) hope that it will help guide action.

This example places into sharp relief the major differences between problem-centered and solution-centered processes:

- The former sets up an expanding "work increases to exhaust the allotted time" dynamic, whereas the latter already starts from an expansive view and

continually narrows the analysts' sights to converge upon a conclusion. When the goal is to "understand the problem," the finish line can recede faster than the movement toward it, whereas when the goal is to identify the best available solution, the analysis has a natural and hard-to-miss stopping point: the point at which further analytic refinement would not change the decision.

- A series of solutions to components of a problem can provide incremental benefits, and perhaps can ameliorate the entire problem, without having to wait for full understanding. This makes for an especially dramatic contrast between the two approaches when we misconstrue the problem as a single issue when in fact it is an agglomeration of issues (arguably, we do not face a "dioxin problem", but rather a series of dioxin exposures that each represent related but separable industrial policy problems or environmental design problems).
- Most importantly, real choices are all about navigating a sea of constraints and opportunities, and the current two-step process (assessors opine about a desirable abstract goal, leaving managers to puzzle out a way to achieve it—or to not achieve it) neither exploits real opportunities nor is tethered to real constraints. This applies in spades to environmental risk management, because we can measure and model both risks and costs as continuous variables, but the real-world interventions we might undertake tend overwhelmingly to be discrete and granular. We often apply a mental model of pollution control (or food safety, or natural hazard management) that posits a "visible hand" controlling a dial to reduce exposures until the remaining risk reaches a level of acceptability or cost-effectiveness, but in reality there is no "dial," but rather a series of switches that provide only particularized increments of exposure reduction. It may be interesting to know exactly where we would cease "turning the dial" *if we had one*, but our first priority should be to assess the performance (benefits conferred and costs associated) of the switches we actually could choose to flip, in order to decide which one(s) to engage.[5]

The other important attribute of real decisions involves the interplay between the timing of when solutions are first raised and the breadth of solutions considered. As soon as the mind begins to churn around a problem, *it closes the book on some solutions that can and will never even be considered, because they appear to fall outside the boundaries of acceptable deliberation.* The adage that "when all you have is a hammer, everything starts to look like a nail" may be more instructive when turned on its head: once you call what you have tripped over a "nail," you immediately stop thinking about looking for any tool other than a hammer. The most basic innovation of SFRA is

[5]Note that considering several real solutions is not the same as the practice (common at OSHA, and not uncommon at USEPA) of analyzing multiple abstract goals, such as "the desired exposure concentration along with half and twice that concentration." For example, the 2006 NAAQS for fine particles proposed three "decisions"—the current baseline, a new annual average limit of 15 $\mu g/m^3$, and a stricter limit of 14 $\mu g/m^3$ that USEPA eventually rejected. I hope it goes without saying that this is *not* "evaluating solutions," but "trying out numbers." The optimal solution may turn out to be closer to one of these permutations than it is to the initial pronouncement, but that will only occur by coincidence, not because getting to "half the original proposed limit" is a well-specified means to an end.

that it starts by looking not at substances or hazards or risks as problems, but as *opportunities for change*. Risks arise because sources of risk exist, and arguably the job of the risk manager is to go back to the source and ask how changing it can create a future with substantial and varied increases in net social benefit. Asking the opening question in new and different ways opens the door to new and different outcomes, ones that simply cannot emerge from the "acceptable exposure to a single risk factor" paradigm.

Therefore, the risk management paradigm presented here challenges decision-makers to take the first step—to envision possible interventions that might achieve an array of social goals—and then to turn risk scientists and economists loose to amass information on the pros and cons of each possible intervention. The process does not stop there, and it contains many elements that will strike critics as familiar and uncontroversial, but this basic insistence that (tentative) solutions should precede conceptually the detailed dissection of problems calls into question the wisdom of much of the effort, time, expense, and accomplishments of risk assessors and managers in the nearly 30 years since the Benzene decision and the "Red Book" launched the era of risk-based governance.

OBJECTIONS THAT DO NOT APPLY TO THIS PROPOSAL

Before discussing (in the "Serious Concerns" section below) various thoughtful and sobering criticisms I have heard raised about these ideas, it may help to clarify several of the possible objections that do *not* apply, only because they presuppose a version of SFRA that I already realize would be unworkable or unwise, and do not intend. There are enough obstacles to creating a solution-first mindset, where appropriate, without adding concerns based on a misperception of the concept:

- *SFRA is not intended to fully displace the traditional problem-centered approach, but rather to complement it in some settings and defer to it in some others.* There will always be a need for untethered risk assessments designed to increase our understanding of potencies, exposures, and risks, and there will always exist agencies such as the U.S. National Institute of Environmental Health Sciences (NIEHS) whose missions do not include implementing solutions. The names of these agencies do not include words like "protection" and "safety," words that suggest a mission that ought to go beyond "problem formulation." Even in the regulatory agencies, some activities are better suited to (or currently constrained by statute to follow) problem-focused thinking. And even if an agency embraces SFRA for a particular activity, thinking about solutions should occur in parallel with thinking about problems: doing the latter should help refine or expand the range of solutions contemplated, and doing the former should help refine the areas of uncertainty that need to be resolved in the risk or cost analyses. I think it is a useful metaphor to consider the two approaches in terms of a "gestalt diagram" like the familiar picture of a champagne goblet whose left and right borders also form the outlines of two faces looking at each other: it takes mental discipline (especially if you have been looking only at one part of the picture for too long) to be able to switch between perspectives

at will—in this case, to recognize that the risks we study are both problems and opportunities.

- *Identifying an optimal solution does not imply that the risk manager should or can require anyone to implement the solution.* Many critics of government regulation reserve special ire for rules that specify the means of compliance. However, government certainly can determine which solution would in theory maximize net benefit, and yet not have the authority to force its adoption, or choose not to exercise such authority. This would not at all make solution-focused analysis a waste of effort, but might reflect a reasoned belief that more good could be done via a voluntary regime or through market forces acting in light of new information on risks and costs. But if merely discussing a preferred solution can be attacked as coercive, then both SFRA and the traditional process will draw fire; both of these decision-making paradigms are intended for societies that have evolved beyond anarchy.
- *SFRA does not presuppose a single "right answer."* There is admittedly some arrogance even in striving for the relatively best approach to a dilemma, but "solution" is meant here in the sense of many ways to ameliorate a situation, not the single conclusion that must supplant all others (as in the usage of that word in submarine warfare, where the task is to plot *a* "solution" to guide weapons fire). A well-designed SFRA process should admit proposed solutions into the mix during the analysis (informed by an improved understanding of risk), and should "look back" to ensure that the intervention(s) chosen is delivering the benefits expected and to explore if new ways of doing even better had arisen in the meantime.
- *SFRA only makes sense in situations where risks and/or costs matter.* If a given decision must be made by random chance, by an uninformed power struggle, or by total unwillingness to change the status quo, then SFRA will be a waste of time—but then so would any form of risk assessment.
- *SFRA explicitly allows for "leaving well enough alone."* The word "solution" is intended to encompass situations where doing nothing is the best alternative. However, there is a world of difference between doing nothing out of procrastination or denial, versus doing nothing because all other alternative were found to have smaller net benefit or larger net cost.

ECHOES OF SFRA IN FAMILIAR PLACES

SFRA borrows and assembles many of its features from processes that others have already invented, and that readers may see as familiar and useful. Table 1 summarizes some parallels from disparate areas of study and practice.

SFRA seeks to carve out a niche within the more closely related areas of environmental policy and regulatory design. One way to think about SFRA is as a synthesis of some of the features of lifecycle analysis (LCA), cumulative risk assessment (CRA), and "beyond risk" processes devised to set broad agendas for environmental protection and other social priorities. With respect to LCA, SFRA merely adapts it to social interventions that government can require or set in motion, as opposed to choices individual producers or consumers can make on their own; within the subsequent analyses, it can then apply concepts of CRA to evaluating *changes* in risk (and cost)

Table 1. SFRA has echoes in familiar places.

Analogous area	Term of art used	Example
Decision theory	"Value-Focused Thinking" (Keeney 1992)	An unexpected phone call from a rival company offering you a job does not create a "should I stay or move to the rival?" problem, but a "what do I want to do with my career?" problem—there are more than two options here.
Clinical medicine	Primary prevention	A patient whose pants are too tight should not be advised to buy larger pants, but to consider one or more lifestyle, pharmaceutical, or surgical interventions to control his weight.
Clinical psychology	"Solution-Focused Therapy" (O'Hanlon and Weiner-Davis 1989)	The patient is asked to imagine all his problems were solved as if by a miracle, and asked to articulate how he would *know* that the miracle had occurred; seeing the signs of change can reveal concrete steps to effect change.
Business quality control	"TRIZ" (Russian acronym for "Theory of Inventive Problem-Solving") (Domb 1997)	The "ideal final result" is a new way to fulfill the product's function that eliminates rather than marginally reduces accompanying risks—*e.g.*, grass genetically engineered to grow only to a certain height could avoid the pollution, noise, and danger posed by lawnmowers.
Ecology	"Solving for Pattern" (Berry 2002)	Designing, *e.g.*, agricultural production processes to emphasize "repairability, redundancy, locality, and simplicity" (Orr 2007).

rather than to improving our understanding of the status quo of risk or cost. So, for example, while LCA might compare the panoply of health and environmental effects of paper grocery bags versus plastic ones (Schnoor 2009), concern about a signal of harm from a substance found in plastic bags might spur an SFRA exercise that would evaluate various ways to minimize exposure to that substance, *including* policies that would discourage the use of plastic bags. In all of the comparisons, CRA could improve the risk-based assessment of solutions by considering incremental exposure to the substance under various policies, in terms of the concomitant exposures to that substance from other sources (or exposures to other substances believed to act via the same biochemical pathway(s) to increase the risk of a particular health endpoint). Unlike the typical CRA, however, SFRA would also explore the risk implications of policies that would increase the use of substitutes for plastic bags, and consider the incremental risks from *those* substances in terms of their own baseline CRA.[6]

With respect to priority-setting, SFRA challenges the conventional wisdom in the same way that critics of risk-based priority-setting have tried to focus planners' attention on allocating limited resources to specific actions rather than to disembodied problem areas. Soon after USEPA embarked on risk-based priority-setting with its "Unfinished Business" (USEPA 1987) and "Reducing Risk" (USEPA 1990) reports, several scholars proposed wholly different ways to set a broad environmental agenda that did not treat comparative risk ranking as an end in itself (see Finkel and Golding 1994). The advice that USEPA could instead (or in addition) identify promising pollution prevention opportunities (Commoner 1994), or focus on localities where residents faced multiple threats from overlapping "hot spots" of pollution (Bullard 1994), or develop technology-forcing regulations for industrial sectors that had resisted innovating away from toxic and energy-inefficient processes (Ashford 1994), all derived from the basic orientation that agencies should see their task as how to take the best actions first, which is not at all the same as tackling the "worst risks first." Although USEPA has never undertaken a solution-ranking initiative comparable to its major risk-ranking exercises, U.S. experts have participated in global priority-setting exercises in which they ranked defined solutions to disparate environmental problems that together could be achieved with a given level of expenditure (Lomborg 2004, 2006). The results of these exercises have sometimes been misinterpreted to denigrate the importance of problems such as global climate change, when in fact the rankings reflect a set of views about the net

[6]Some signs now point to an interesting watershed in the policy uses of CRA. Part of the original impetus for CRA was to focus more attention on small increments of exposure from anthropogenic sources when they are found to add to a background exposure (to the same substance) that already puts some people near or above adverse-effect (or significant-risk) levels. However, one could instead view these incremental exposures as *less* of a priority if consumer or lifestyle choices can make a bigger dent in the background. For example, a recent USEPA report on perchlorate in the environment concluded that providing supplemental iodide might be more effective in improving thyroid health than environmental controls on perchlorate emissions or cleanup of existing sources (Renner 2010). SFRA facilitates this latter way of looking at cumulative risk situations, without suggesting that "victim-level" measures should ever be preferred to source-level ones.

benefits of particular interventions, some of which effectively eliminate "smaller" problems and others of which chip away in cost-effective ways at much larger problems. "Ranking the Opportunities" (Lomborg 2004, pp 605–644) is exactly the spirit of SFRA. Doing so will also respond to the concern that SFRA regards "everything as important"; to the contrary, those solutions that offer large net benefit are the most important.

Aficionados of the regulatory design literature and observers of regulatory policies should also recognize SFRA as entering into the long-standing tug-of-war between performance-based standards versus design- or technology-based ones (with "technology" here intended to cover the various means of effecting risk reduction, including substitution, personal protective equipment, lifestyle changes, etc., not necessarily end-of-pipe hardware). *But it is crucial to understanding SFRA to recognize that, while it views pure performance standards with suspicion, it also aspires to reform technology-based standards as they have come to be developed*. Focusing on solutions is not at all the same as dictating technological choices.

To conclude, as I have above, that "a NAAQS or a PEL is not a true decision at all" certainly displays a mistrust of performance standards expressed as single-substance exposure limits. Industry has typically taken the opposite view, advocating for performance standards over design standards on the grounds that central planners cannot possibly design methods of compliance to achieve a given level of risk reduction at the lowest cost, and should therefore satisfy themselves with setting the bar and letting companies reach the performance goal in the efficient ways only they can devise (Ackerman and Stewart 1985; Latin 1985; McCubbin 2005). But the most vociferous (and successful) industry condemnation of a federal regulation in my experience was directed at the OSHA ergonomics rule that took effect in 2001 (US Department of Labor 2000), and although that rule had many procedural and substantive flaws along with its many strengths, the lion's share of opposition centered on its near *absence* of specific design requirements! (US Senate 2001; Shapiro 2007; Finkel and Sullivan 2011). Small business, in particular, convincingly expressed dismay that OSHA had set performance goals without providing any blueprint(s) for how companies could meet them.[7] For example, the standard required companies that had workers with diagnosed musculoskeletal disorders and that exposed them to one or more "ergonomic risk factors" to reduce those risk factors—but they were instructed to reduce them below levels found somewhere within eight external (and sometimes conflicting) documents referenced in the standard, or to reduce them "to the extent feasible."

By its very nature, SFRA develops and compares design outcomes. In that sense, SFRA would definitely shift the balance toward specifying the means of compliance.

[7]For a representative reaction to this "user-friendly" performance orientation, consider the floor statement of then-Senator Tim Hutchinson (R-AR), urging his colleagues to strike down the ergonomics regulation: "The rule is replete with vague and subjective requirements where employers must have an ergonomics plan in place to deal with such hazards. OSHA said it is being flexible by allowing employers to design a plan that caters to their own workplace, but that same 'flexibility' also requires the employer to be an expert on ergonomic injuries."

However, I personally endorse the idea of crafting hybrid regulations whenever practical: the SFRA could identify the optimal design, and flowing directly from the risk assessment that identified this optimum would be an associated risk reduction level (a performance goal). A regulation could then give the regulated parties the option of either following the specified design (the "safe harbor" option) *or* of changing products, processes, or uses to yield equivalent or greater net risk reduction.

I also recommend a different and even more important synthesis of performance and design orientation, for which the U.S. Clean Air Act Amendments of 1990 provides an instructive motivation. Over the past 35 years, the U.S. Congress has lurched between requiring USEPA to impose performance-based and technology-based standards for toxic air pollutants. When the initial risk-based regime had only yielded seven emission standards in 20 years, Congress shifted gears in the 1990 Amendments to a technology-based regime, but also foreshadowed a subsequent risk-based round that USEPA is now beginning to put into place. In the first round after 1990, USEPA assessed the relative efficiency of different technologies without regard to how much absolute risk reduction they offered; so far in the opening initiatives of the subsequent round, USEPA has tended to set additional exposure reduction goals without assessing how they will be achieved (and at what cost, and with what effects on other risks). For example, the USEPA (2005) residual risk rule for coke ovens emphasizes a performance goal to limit "allowable visible emissions" to a small specified percentage of the time the units are operating. So the best-available-technology exercise divorced from risk assessment is the how without the why; unless the stars align fortuitously, it can result in "too much technology" (the "best" is very costly and reduces risk well below *de minimus* levels) or in "too little technology" (the best at present is simply not good enough if properly viewed through the lens of risk). The other extreme of a risk-based approach not grounded in technology results, as I have argued above, in "why without the how" aspirational statements. *What is missing here is the logical marriage of the risk-based and technology-based ways of thinking—namely, a risk-based technology options analysis.* SFRA would ask the regulatory agency to probe into the risk-reducing capacity of various specific control options, and to produce a rule that answers both the why and the how. If the best available technology is simply insufficient to reduce risks to acceptable levels, SFRA reveals this in one step rather than the U.S. Clean Air Act model of a decade's worth of suboptimal technology followed eventually by residual risk analysis. If a less expensive control is ample to eliminate or minimize risk, SFRA can stop here, avoiding technology "overkill" and freeing up resources for other issues.

This emphasis on technology options analysis owes a significant intellectual debt to Nicholas Ashford of the Massachusetts Institute of Technology, whose contributions to scholarship and teaching in innovative environmental policy have influenced me and many others. Ashford's vision—that stringent performance standards can "unfreeze" industrial processes that have failed to innovate toward more efficiency, safety, and sustainability—is certainly solution-oriented, and could be used to harness risk analysis in the service of comparing technology options. However, Ashford (2000) describes his preferred approach as "a technology-based, *as opposed to* a risk-based, approach to environmental problems" (emphasis added) whereas I aspire to combine the two, with risk reduction the most important single attribute of technology. Despite some sympathy for the opponents of cost–benefit balancing

(Montague and Finkel 2007), I maintain that (a more rigorous, equity-focused, and humane) analysis of both risks and costs should be our lodestar, whereas Ashford prefers qualitative risk comparisons to extensive quantification, and emphasizes risk minimization as a goal rather than optimizing risk reduction net of control costs. More importantly, his emphasis on "directed innovation" means that we would choose policies today based on what they might deliver tomorrow in terms of new technologies, and this by definition *precludes* a full risk/cost comparison of identified solutions, as I recommend. Confining the solution set to designs whose efficiencies and costs can be quantified today is arguably a weakness and a strength of SFRA in light of Ashford's alternative vision, in which stringency is the goal, rather than the result.

Because other pioneering advocates of technology options analysis have expressed more disdain, or out-and-out contempt for risk assessment (O'Brien 2000), I hasten to emphasize that SFRA does not presuppose that a zero-risk control option is desirable or even exists. This is not an idle observation, because when viewed through the (proper) lens of cumulative risk, even a total ban on a substance or product might increase net risk despite its superficial appeal. But the central parable O'Brien offers—that you should not be advised to wade across an icy river, even if the risks are trivial, when there is a footbridge nearby – tells an important *half* of the story SFRA seeks to tell. Yes, I would add, look at the alternatives, but look through the lens of risk assessment, not the lens of "natural is better" or any other dogma. SFRA demands we open our eyes to win/win options that some may hope we ignore, but it does not expect to find (or to concoct) such escapes when they are not truly available.

EXPECTED BENEFITS OF SFRA

A focus on solutions should yield some obvious classes of benefits, chief among them a portfolio of actions that are more timely and concerted than what we have become used to. But an improved decision process actually offers benefits beyond the promise of better outcomes:

A. *SFRA should give stakeholders opportunities to do what they most want and are best at doing*—to contribute their special knowledge and preferences about decisions, rather than about science and risk. Recommendations from many quarters have emphasized that broadly inclusive decision processes are superior to narrow ones, but they have concentrated more on stakeholder access than on the content of their intended influence. And when content is discussed in the planning of public involvement, it sometimes tends to emphasize either "special local knowledge" of exposure (*e.g.*, the possibility that groups such as subsistence fishers have unique exposures) or special preferences in the abstract (*e.g.*, subgroups who might be particularly concerned about cultural landmarks). Highlighting these sorts of issues in a public meeting is certainly more likely to yield useful information, and less likely to frustrate the participants, than the practice of inviting public comment on arcane controversies around the underlying science. However, more sensible still would be the open discussion of the pros and cons of contrasting solutions to the problem at hand. A step toward such a model for a solution-focused exercise in "civic discovery" (Lipshitz and Mann 2005) was

already pioneered at USEPA, in the form of the "Tacoma process" championed by administrator William Ruckelshaus in 1984.[8] Similarly, many of the public meetings USEPA convenes to discuss remediation options at Superfund hazardous waste sites have promoted "civic discovery" about what to do with past contamination. In the future, USEPA and other agencies could also involve the affected public in the initial arraying of possible solutions to continuing problems where new hazardous exposures will be generated, as well as the subsequent discussion of how information on risks and costs distinguishes the solutions from each other, instead of only involving them in the science and ethics of acceptable-risk determinations. The 1996 National Academy of Sciences "Orange Book" (NRC 1996) emphasized interactions among public officials, technical experts, and the populace to help reach a common understanding of how to "describe a potential hazardous situation in as accurate, thorough, and decision-relevant a manner as possible" (p. 2); SFRA simply suggests that rather than only trying to reach a common understanding of the problem, we should be trying to reach a common understanding of the pros and cons of the choices before us.

B. *SFRA will demand more complete and rigorous analyses, in three fundamental and long-overdue respects,* giving scientists and economists more license to incorporate information hitherto marginalized:
   - moving the endpoint from "acceptable levels of exposure" to "best-performing decisions" will highlight the deficiencies of arbitrary single measures of exposure, in favor of continuous relationships between exposure and consequence. The growing dissatisfaction some risk assessors, and many economists, stress about dichotomous benchmarks such as the Reference Concentration or the Margin of Exposure stems from concern that these measures do not relate to harm or benefit—they merely demarcate a possible "bright line" separating desirable from undesirable, with no quantitative relationship between the two. Various expert groups (see, *e.g.*, chapter 5 of NRC 2009) have recommended strongly that USEPA and other agencies develop parallel (or "unified") dose–response assessment processes for carcinogenic and non-carcinogenic hazards, in part so that decision-makers and the public can evaluate the benefits of those exposure reductions that move some individuals from above a benchmark concentration to below such a line. More importantly, the current approach leaves us powerless to even take account qualitatively of all those exposure reductions that do not "cross the line" (*i.e.*, the benefits of moving from an exposure well above the benchmark to an exposure closer to but still not below it, or of moving from below the benchmark to a level further still below it). *Any risk management process that requires that we compare the benefits of available control options will drive the demand for these more useful, and arguably more scientifically appropriate, methods of assessing toxicologic potency and risk.*

[8]Ruckelshaus convened a series of public meetings in the neighborhood around a highly polluting copper smelter near the city of Tacoma, Washington, so that USEPA and the affected public could "determine together what is an acceptable risk from arsenic emissions" (Lipshitz and Mann 2005). The smelter closed down due to declining global copper prices before the discussions were complete, but reportedly much progress was made toward a common understanding of the risks of the status quo and the costs of emission reductions.

- SFRA puts risk-risk tradeoffs front-and-center, forcing decision-makers to confront offsetting risks before they create them, rather than having to backpedal after the fact. The contrast between substance-focused risk assessment and SFRA is particularly stark when regulating the substance turns out to encourage substitution to a more toxic material—*a quintessentially perverse outcome to which the traditional PEL/NAAQS process is oblivious*. If, as I and others argue is not infrequently the case (Finkel 2007; Tickner and Gouveia-Vigeant 2005), multiple interventions could readily reduce both the primary and the offsetting risks, then surely it is far more sensible to analyze these tradeoffs up front and design an optimal approach taking net risk into account, rather than chasing after new risks created by clumsy interventions (see, *e.g.*, the new Philadelphia regulation (City of Philadelphia 2010) controlling both the most common solvent used in dry cleaning and a newer and arguably more toxic substitute).
- SFRA makes more visible what we often consider covertly—the costs of control. SFRA will demand more rigor in how we estimate costs, thereby helping fix the weakest link in all of quantitative environmental analyses. Defined actions to reduce risks have costs, as do promises that risk-based goals will be met through some undetermined future actions—but it is much easier to gauge whether the actions will yield risk reductions worth their cost if they are chosen through the comparing of alternatives that SFRA impels. Inattention to cost can lead either to over-regulation or to under-regulation, with the latter occurring both across-the-board (through the well-documented tendency to exaggerate costs (see, *e.g.*, Harrington *et al.* 2000) and in important aspects of the scope of specific regulations (where tacit consideration of costs results in exemptions, variances, and lax treatment for sectors of industry that impose high risks whose reductions would be costly to them). In an ongoing series of projects, colleagues and I are documenting the lack of attention in regulatory analysis to uncertainty and inter-individual variability (in the sense of the share of total cost borne by individuals and subpopulations of consumers and producers) in cost, especially as compared to the increasing rigor with which risk scientists now routinely estimate uncertainty and variability in risk (Finkel *et al.* 2006; Finkel 2009). Even if SFRA does not add back into the solution set various options that were excluded before their large costs were ever compared to their huge benefits, the act of starting the cost estimation process earlier should improve it, to the extent that the lack of rigor in regulatory economics is due to the "11th hour" nature of this activity at present.

C. *SFRA can help society embrace uncertainty and make the best of it.* SFRA can help us confront uncertainty as the ally it should be to effective policy rather than its adversary. For the important cases when *model uncertainty* makes it impossible to know which of two or more dramatically different estimates of risk is correct, there are logically only three basic ways to proceed: (1) put the model uncertainty to the side, giving one "default" model at each inference point primacy over all alternatives, until an alternative assumption or model becomes compelling enough to supplant the default; (2) construct a hybrid risk estimate (or a hybrid uncertainty distribution) by averaging together the various point estimates or distributions, weighted by the degree of belief assigned to each; or (3) do it the way decision theory instructs—namely, *assess the pros and cons of different decisions,*

in full light of the multiple possible risk estimates. Because I see the second option as so wrong-headed, I have worked to improve the first option, trying to help regulators (particularly those at USEPA) to finally develop a common-sense and transparent system for evaluating default assumptions versus alternative ones, out of the current morass of confusion USEPA has created around this issue (NRC 2009, chapter 6, esp. footnote 2). But risk estimates that place zero weight on all inferences other than the default are admittedly overconfident by definition, and SFRA simply handles the model uncertainty correctly rather than incorrectly. When the risk is either of magnitude A (with probability p) or B (with probability $(1\text{-}p)$), it is incorrect for the risk assessor to cause the decision-maker to act as if the risk was known with certainty to equal $[p\text{A}+(1\text{-}p)\text{B}]$, but this is exactly what most proposals for model averaging do (Evans *et al.* 1994; Cooke 2009). Assessors need only ask this simple question rather than the fatuous one: if the risk is either A or B, how does solution X perform against a risk of size A or size B, as compared to how solution Y would perform? Consider, for example, a risk that is either "huge" (under the default assumption, perhaps that rodent tumors are relevant to humans) or zero (under a plausible alternative assumption). The "risk-first" process misleads the decision-maker into worrying about the acceptable exposure to a risk of size "p times huge," whereas SFRA asks instead whether ignoring a huge risk (with probability p of making that mistake) is better or worse than the cost of eliminating a non-existent risk (with probability $(1\text{-}p)$ of erring in that way). To be sure, it might sometimes be best of all to reduce the risk by a factor of $(1/p)$, because that action may have a smaller expected loss than either of the two strategies that might actually be correct, but that kind of compromise should arise out of a thoughtful weighing of consequences rather than as the inevitable result of a process guaranteed to mislead.

SFRA also may be the only way to correctly open the door to an enormously useful category of real decisions—those in which *gathering more information* emerges as preferable to deciding now. Formal value of information (VOI) methods (Yukota and Thompson 2004; Finkel and Evans 1987) require that the decision options be specified. Indeed, the crux of VOI theory is that information has value *only* insofar as armed with it, one can reduce the probability or consequence of choosing a decision that is inferior to another available choice. This is very different from putting research money into "interesting" questions, or into the largest uncertainties, which is the thought process that often passes for systematic these days (Finkel *in press*). VOI theory insists that seeking information that could potentially change the rank ordering of solutions is the most valuable—indeed, the only valuable—way of spending one's time short of deciding.

ADVANCES IN DECISION-MAKING PROCESSES THAT DO NOT CONSTITUTE SFRA

Although observers have raised various serious concerns about the wisdom of SFRA (see the next section), it may actually face more obstacles to ever being tried

out from assertions that it is already being done or that it has already been proposed elsewhere. Several recent sets of recommendations for changing risk-based decision-making are creative, visionary, and responsible for opening doors to solution-focused ideas—and each may well be superior to SFRA in some or all respects—but they do *not* propose SFRA as I describe it here, and some cases they may in fact be its antithesis. Listed in Table 2 are some prominent cases in point.

SERIOUS CONCERNS, AND PARTIAL COUNTER-ARGUMENTS

The steps that *Science and Decisions* (NRC 2009) made toward earlier consideration of risk management options have aroused criticism (Hegstad 2008), and the more expansive concepts of SFRA I have advanced have prompted objections in several public forums over the past two years. I offer here a partial catalog of the more portentous concerns that have been raised, along with some attempts at rebuttal and synthesis.

1. *SFRA will exacerbate the existing "inappropriate over-involvement on the part of political risk managers"* (USEPA's Peter Preuss, quoted in Hegstad 2008), *perhaps leading to the kind of corruption the Red Book committee worked so hard to identify and minimize.* I agree that this could be a serious flaw of SFRA, but I do not agree that a discussion of solutions could be "hijacked" any more readily than could any discussion of hazards and risks. There is no question that a corrupt SFRA process could yield corrupt results: it would be farcical or worse if risk managers were allowed to instruct assessors to "evaluate the pros and cons of options A, B, and C, but you had better make sure C comes out on top." But there is nothing about asking the question this way that increases the risk of corruption over the current process, in which managers could instruct (and certainly have at times instructed) assessors to "assess the risk of substance X, but you had better make sure to conclude the risk is trivial (or failing that, at least to 'lowball' it as much as possible)." One also needs to weigh both worst-case outcomes—under SFRA, the implementing of risk management decisions that parrot the political will of elected or appointed officials versus under the current process, the (eventual) completion of pristine assessments that may lead to no risk reduction activities at all.
2. *Agencies are often forbidden by statute from analyzing the risks (and costs) of defined options, but must study risks in isolation before contemplating solutions.* The universe of situations where an agency chooses not to conduct a particular analysis is much broader than situations where laws or court decisions actually have forbidden it from doing so (Sunstein 2002). Even where an agency is required to produce a free-form risk estimate, as in the NAAQS process, it could still do so after thinking expansively about solutions, in effect conducting both a solution-focused exercise and a generic (risk per unit exposure) analysis in parallel, and shunting the former into a public-information exercise. Some statutes may need to be amended for a concept such as SFRA to make major inroads, but some see that as an opportunity rather than a negative (Flournoy and Driesen 2009; Kysar 2010).

Table 2. Noteworthy advances in decision-making processes that do not amount to SFRA.

Report	Major recommendation	Major difference vis-à-vis SFRA
NRC (1996)	Risk assessment should "serve the needs of decision-makers"	Meant here in the sense of "decision-makers may tell risk assessors which problems to work on"—*not* which solutions to evaluate the costs and benefits of.
PCCRAM (1997)	"Define the options" is the third (of six) steps in the framework	Discussion of options occurs only after risk assessment is well underway or completed; "holistic" assessment is often touted as a way to ignore relatively small sources of risk, rather than to reveal options that reduce these and other sources in tandem.
NRC (2005)	"The first step is that a decision be defined, and second that a list of decision alternatives from which to choose be considered"	Definitely a solution-focused mindset, although in context this report envisioned binary choices (specifically, should a given type of radioactive waste be stored in a deep repository or not) rather than multiple, continuous, or multi-agency solutions.
NRC (2009)	"Risk assessment is of little usefulness . . . if it is not oriented to help discriminate among risk-management options"	Clearly based on concepts in USEPA (1998), but "problem formulation (PF)" is perhaps the antithesis of thinking about solutions.[1] A properly "formulated" and "scoped" risk assessment is better than an inchoate one, but it may never evaluate *any* solutions, let alone ambitious ones that consider life-cycle impacts, cumulative impacts, and multi-agency collaboration.

[1] In discussions with other members of the *Science & Decisions* committee, it was clear that a few members saw a possible way to reconcile the seeming opposition between beginning risk assessment with a formulation of the problem versus an enumeration of possible solutions: if the "problem" to be analyzed can be defined as "the lack of a good solution," then my insistence that PF precludes SFRA may be overly pessimistic. However, I believe that the current USEPA definition of PF, as expressed in its Ecological Risk Assessment guidelines, does not allow for this happy reconciliation of views. To USEPA, PF occurs when "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined." I have no doubt that it is better to have a plan for analyzing risk, grounded in some understanding of the sources of the problem, the laws and policies that surround it, and the time and resources available to analyze, than to "hit the ground running" and analyze risk without such grounding. But this is not "solution formulation" in any meaningful sense. I think it is unfortunate that the *Science and Decisions* committee chose in our key Figure 8-1 (the "new framework") to make the heading for the first phase of the process "Problem Formulation and Scoping"—I worry that this word choice may signal to USEPA that it is already following the new framework, and that this will help ensure that no transition to anything like SFRA is actually made.

3. *Because "he who controls the options controls the outcome," SFRA (further) skews the power structure away from the affected citizens and their public-interest guardians, and toward the regulated industries.* This criticism has significant merit, as some of the crucial information about solutions (their very existence, as well as their costs and efficacies) may be closely held by the regulated community, and injected into the process strategically. Some of the same concerns have always applied to risk information, but in theory the independent replication of toxicology testing or exposure monitoring could be undertaken. So in the spirit of a win/win response, a sensible reaction to this problem might be for the agencies to subsidize the participation in solution-generating exercises by representatives of the public. I also note that some of the "unequal distribution of power" argument is reminiscent of similar concerns environmental groups have raised about risk assessment itself over decades, and that some of this asymmetry may be deliberate and self-fulfilling (Tal 1997; Revesz and Livermore 2008).
4. *The explicit rationale for choosing a solution (and for rejecting others) in a regulatory processing is fodder for litigation challenging the decision.* In my experience, the risk-aversion of government lawyers has stymied sensible attempts to make regulations more stringent, participatory, and transparent. Despite a general tendency toward judicial deference, the lawyers' job does remain that of reducing the probability of ending up with no standard at all. But the same sorts of objections have long been raised about the efforts by risk analysts to be more honest about uncertainty, and courts increasingly now seem to appreciate that acknowledging uncertainty is not a sign of weakness in the analysis—so showing more of the logic behind a choice among solutions may create a "virtuous circle" that increases judicial and public tolerance for ambiguity and for optimization in the face of uncertainty.
5. *SFRA makes risk assessment harder to do.* Former EPA Assistant Administrator George Gray made this point at the Society for Risk Analysis annual meeting session on SFRA in December 2008 (Hegstad 2008), suggesting that once decisions are compared, deficiencies in how uncertainty (especially model uncertainty) is quantified become more apparent and more debilitating. I agree, but I see this as a strength of SFRA, both *per se* and for how it might help lessen the long-standing mismatch between the enormous financial and human stakes of making sound risk management decisions relative to the meager resources we devote to conducting and improving risk and economic analysis (Finkel 1994).
6. *SFRA "dumbs down" risk assessment.* Some may object to putting the brakes on risk assessment when uncertainty has been reduced enough to confidently make an informed decision. I respond that "settling" for less than exhaustive knowledge about risk in no way demeans the assessment. To the contrary, when the goal is to know enough about risk-reduction benefits to choose wisely, it will no longer be acceptable to exhaustively claim to pinpoint a non-risk measure such as a reference concentration or the margin of exposure—risk assessment will have to grow "smarter" in order to express the science in metrics that relate to expected improvements in human health or the environment (NRC 2009, chapter 5). But it will be important to make sure that assessors are not thwarted from continuing to refine their understanding of risk just because they may have reached a point in an immediate decision problem where they

know enough to present the results of a risk-based comparison of decision alternatives.

7. *Assessments performed for an SFRA may be useless for other purposes, leading to widespread and wasteful duplication of efforts.* According to Gibb (2009), "when risk assessments are tailored to specific problem sets and circumstances, the immediate decision may be served extremely well, but there may be a tradeoff that erodes the common applications of these types of assessments elsewhere." I agree, and urge that the "science agencies" be expanded and encouraged to provide more raw materials (dose–response assessments for substances and mixtures, exposure assessments for industrial processes and products) that can be adapted to jump-start solution-focused assessments that the regulatory agencies will undertake. Duplicate risk assessments are already a growing problem in the current environment, of course, in which disparate agencies (and even programs within a single agency) seem reluctant to take advantage of work performed elsewhere.
8. *It makes no sense to array any solutions before you know what the problem is.* Because I believe the balance is currently tipped so much in favor of dissecting problems and considers solutions too late in the game or not at all, I have emphasized the inverse of this process. I do not agree that it is nonsensical to begin by mapping the "signals of harm" back onto the products and process from which they emerge, and by considering tentative ways to improve these processes in risk-reducing ways. But again, the early step of expansive thinking about solutions should promptly return to re-grounding the endeavor in traditional problem-focused thinking—and thence to a recursive process in which more information about risk refines the solution set, and more information about solutions directs the analysis toward specific knowledge gaps and uncertainties. If either strain of thinking proceeds for too long without the other, the process will suffer. However, while "too much" thinking about solutions may turn into idle daydreaming, "too much" fixation on problems may foreclose opportunities to design the interventions that will in fact yield the greatest net benefit—which I assert is a more unfortunate outcome.
9. *Specifying the means of compliance freezes technology, leading to less risk reduction in the long run.* In theory, this drawback of SFRA concerns me more any of the others mentioned so far; the literature contains many criticisms of technology-based standards for inherently ordaining that "the best we can do now" is more important than continuous improvement (Dower *et al.* 1997; but see Wagner 2000 for a contrary view). But there are reasons to be less enamored of the opposite idea (risk-based performance goals) in light of the new potential of SFRA: (1) in the past, technology-based standards have not generally had the risk-based check and balance I advocate here—so if current technology is ample to reduce net risk to acceptably low levels (as indicated by a thorough risk assessment), there should be no concern about "locking in" *that* level of pollution; and (2) do performance goals *really* "unfreeze" technological innovation? Many risk-based limits could be tightened over time to spur further control technologies, but in practice the limits themselves are "frozen" by lack of agency attention and political will (OSHA, for example, has only returned to tighten three of its own PELs in its 40-year history). USEPA

has tightened some of the NAAQS limits for criteria pollutants, but it is not clear how often the periodic moving of the bar has spurred innovation, as opposed to cases where innovation emerged independently and *allowed* USEPA to move the bar. Continuous improvement requires continuous vigilance, and I think that is more a function of resources and will than the type of regulatory instrument.

10. *Government should be doing less "central planning," not (much) more.* Now is surely an inopportune time, perhaps even a tone-deaf time, to be proposing something that could be dismissed as "socialism." In addition to the ideological battle lines SFRA may draw, less visceral concerns have long been expressed about the appropriateness of government meddling in technological choices and the inefficiency of interventions that do not encourage "flexibility" among means of compliance by firms and sectors with very different economic characteristics (Wilson 1994). I support a brand of SFRA that considers marketable permits, hybrid performance-specification standards (see the 'Echoes of SFRA in Familiar Places' section above), and other "many sizes fit all" approaches among the solutions that should be evaluated. As to the ineptness or effrontery of government assessing technologies, I can only point out that society picks "winners and losers" all the time in other arenas of social policy. Among the substances that can produce mild euphoria, we allow (and subsidize some of the ingredients of) beverage alcohol, but we generally criminalize marijuana. Among the products of the firearms industry, we draw a line that puts handguns and hunting rifles on one side, and machine guns on the other. We do all this *without* conducting any cost–benefit analyses (considering neither the consumer and producer surplus if banned products were decriminalized, nor the health risks of legal products)—so what would be so odd about promoting (or regulating) one type of light bulb over another, with the *help* of risk and cost information?
11. *We are doing well enough without a new decision-making paradigm.* If our progress is laudable toward reducing environmental, health, and safety risks, then any meddling with the current system is a risky attempt to fix what is not broken. There is some support for this proposition, especially when one looks at the variety of key environmental indicators that have moved steadily in the right direction since 1970, such as the 92% drop in airborne lead, the partial or full controlling of 96% of the roughly 2,000 highest-priority contaminated landfill disposal sites in the U.S. between 2000 and 2008, or the increase since 1990 from roughly 80% to roughly 90% of the U.S. population served by community drinking water systems that had no reported violations of any health-based drinking water standards.

On the other hand, there are various areas where lack of progress suggests there is a need for a new decision-making paradigm:

- Other trends in environmental concentration are not so favorable: some of the criteria pollutants other than lead have fallen slightly on average, but less so at the upper ends of the distribution (the 90th percentile of measured PM_{10} concentrations in the United States fell only from 113 $\mu g/m^3$ to 88 $\mu g/m^3$ between 1997 and 2008, and the same measure for ozone only fell from 194 $\mu g/m^3$ to

174 $\mu g/m^3$), while NO_x levels continue to rise across-the-board. Some of the air toxics concentrations have not declined at all (1,3-butadiene levels were stable from 1994 to 1998). More importantly, atmospheric CO_2 level has steadily risen from 326 parts per million by volume (ppmv) in 1972 to 386 ppmv in 2008.

- Indicators of progress in other areas of risk management have reached an asymptote (as in the number of fatal occupational injuries) or are increasing (as in the number of foodborne illnesses, and the concentrations of many workplace contaminants).
- Trends in disease incidence and mortality reveal a mixed record, with decreases in many cancers among adults offset by increases in childhood cancers, and rates of asthma, autism, and other conditions increasing beyond what improved detection or reporting can likely explain.
- But all of these metrics evaluate only half of the evolution in environmental management. Since SFRA is about opportunities, it is fair to ask also whether the *sources* of environmental stress are evolving relative to reasonable expectations. The gold standard for rapid technological innovation since 1970 has been the breakneck pace of improvements in computer technology: today's $400 desktop has 20 million times the storage capacity, 2 million times the random-access memory, and 2,000 times faster processing speed than the computer that guided Apollo 11 to the moon in 1969. And yet:
- 210 of the 1045 make/model combinations of cars sold in the U.S. in 2003 achieved lower miles per gallon than the 1979 Cadillac Eldorado;
- 65% of U.S. homes are poorly insulated, wasting billions of gallons of fossil fuels annually;
- We still dry-clean clothes using chlorinated solvents, which create risks even in homes far from laundries, just from the exhaled breath of workers when they return home at night (Aggazzotti *et al.* 1994) (and the USEPA "phaseout" of perchloroethylene by the end of 2020 applies only to cleaners co-located in residential buildings, not to free-standing establishments or cleaners that emit into adjacent workplaces);
- In 1970, the major sources of drinking water in the United States were the kitchen sink and the water fountain: today, we in the United States purchase roughly 35 billion plastic bottles of water each year, with implications for energy use and human health.

We may content ourselves with the pace of innovation in products and processes that impact on the environment, but surely a decision-making paradigm that dares to ask the question "can it be done better?" is not outlandish given how uneven the rise of new and better ideas has been across the various sectors of the economy.

ORGANIZATIONAL CHANGE TO IMPLEMENT SOLUTION-FOCUSED ASSESSMENT

In order to increase the ability of national and state agencies to manage in a solution-focused manner, agencies will need to craft new guidance documents, create organization-wide teams to pick targets for innovative decision-making, and

develop the technical and communication skills necessary for managers and assessors to collaborate more productively. In addition to these improvements, however, more fundamental organizational change may be necessary. One current proposal for the creation of a "Department of Environmental and Consumer Protection" (Davies 2009), incorporating six existing agencies and adding bureaus to conduct environmental and health surveillance, emphasized the ability of such an organization to regulate products (as opposed to substances *per se*, which may make less and less sense as new nanomaterials emerge whose risks depend completely on how they are incorporated into finished products) and to produce "social impact statements" of the impacts of technologies.

In addition to bold ideas such as those Davies (2009) has put forward, I urge serious thought be given to a somewhat less sweeping organizational change: the creation of a true interagency risk management collaboration mechanism. In the United States, this could be done either under the auspices of the White House Office of Information and Regulatory Affairs (OIRA) or (preferably, in my view) under an expanded White House Office of Science and Technology Policy (OSTP). So many of the solutions that one agency impels can affect risks in other agencies' purview—and/or can put society on a path that makes opportunities for future risk reduction in another area more expensive or impossible—that it seems bizarre for the environmental, occupational, transportation, energy, housing, agriculture, and other functions of government to pursue separate regulatory and informational agendas. Past OIRA administrators have claimed interagency collaboration among their priorities and achievements (University of Pennsylvania 2006), but in my limited experience (as OSHA's representative to several of these groups between 1995 and 2000), while there was extensive collaboration around legislative issues (notably regulatory "reform" proposals), the problems that involved risk transfers, duplication of effort, or inconsistent requirements across two or more agencies were rarely an opportunity for true collaboration; rather, they prompted OIRA to orchestrate one agency's acquiescence to the plans of another. In contrast, brainstorming about solutions and opportunities could flourish if OIRA or OSTP was willing to "prompt" agencies to work together on interventions whose ideal solutions depend on multiple perspectives, and to develop their own plans to solve problems revealed by, or exacerbated by, the actions of another agency. The notion of a "forest group" looking broadly at options to minimize contradictory interventions and increase win/win coordination is reminiscent of the proposal then-Judge Stephen Breyer made nearly 20 years ago (Breyer 1993). Breyer advocated for a "coherent risk regulatory system" that would involve far more meaningful interagency collaboration than harmonizing allometric scaling (USEPA 1992), or agreeing not to comment on another agency's rule, although he did not mention a solution-focused approach to risk management or a central role for the public in technology options analysis (Finkel 1995).

A SPECIFIC EXAMPLE

Although they were not included in the main body of the report, the ***Science and Decisions*** Committee (NRC 2009; Appendix F) did publish three short case studies

of how increased attention to solutions could change risk-based decision-making. The first case study involved a hypothetical discussion of locating a new power plant in a low-income neighborhood, and the second contained a brief discussion of continuous improvement in maintaining a community drinking water system.[9] The third case study also brings in issues of risk-risk transfer and life-cycle solutions, and here I expand upon the brief description I wrote for ***Science and Decisions***.

Suppose that USEPA and OSHA were each considering how to reduce human exposures to methylene chloride (MC), and were considering (on their own accord or by prompting from a coordinating council) working jointly on one important source of MC exposure: the stripping of paint from aircraft.

Depicted in Table 3 are four different kinds of risk management questions the agencies could ask, moving from the least to the most solution-focused and from the narrowest to the broadest range of solutions. The first two rows depict the traditional substance-specific (and bureaucratically compartmentalized) approach: each agency separately sets an exposure (or emissions) limit for this operation. The only technical analysis required for this decision is a dose–response assessment, although at OSHA, if the aircraft repainting sector was the single one that had the most difficulty meeting the one-size-fits-all PEL for MC, the agency might have to ensure that the technology to achieve the PEL was economically feasible for this sector. The imposition of the exposure-limit solution could result in adequate compliance (which would have to be verified by chemical sampling and analysis), or in non-compliance, or in any of at least three kinds of unfortunate risk-risk tradeoffs: (1) the repainters could substitute a more toxic material for MC[10]; (2) depending on the vagaries of economics and enforcement, they could comply with the USEPA requirement by decreasing ventilation in hangars or spray booths, or with the OSHA requirement by increasing it—either way, transferring exposure to or from the workplace rather than reducing it (USEPA *et al.* 1999); or, (3) they could repaint less often, which conceivably could result in mechanical defects underneath the paint going unnoticed.

The third row of Table 3 is a highly simplified summary of technology-based thinking uninformed by risk analysis: the controls already used elsewhere in this sector are presumed to be affordable, and compliance is presumably more likely

[9]An op-ed (Morris 2007) tackled the safe drinking water problem from a novel solution-focused perspective: the author suggested that drinking water could be made even safer via the installation of point-of-use filters on household taps used for drinking and cooking water, while taps used for laundry and toilet water could instead meet a slightly relaxed set of contaminant levels. This idea sprang from the question "how can we provide water safe enough for its intended use?" not from "what is the acceptably safe concentration of each substance in household water?"

[10]This is a highly plausible scenario—for example, after OSHA's MC regulation was promulgated in 1997, manufacturers began aggressively touting an unregulated substitute (1-bromopropane), despite its known neurotoxic properties and close structural relationship to several animal carcinogens (Majersik *et al.* 2007). The brominated material has caused neurological damage when used as a substitute for perchloroethylene in dry cleaning (CDC 2008), and has emerged from the testing process as a potent animal carcinogen (NTP 2009).

Table 3. Risk-only, technology-only, and solution-focused thinking compared.

Opening question	Analyses required	Agency pronouncement	Likely response(s) by regulated
(USEPA): What is the exposure that creates a risk of 10^{-6}?	Toxicologic potency	Outdoor air shall contain no more than X ppb methylene chloride (MC)	• non-compliance • more toxic substitute • decrease ventilation (but increase worker exposures) • (waste disposal problem remains)
(OSHA): What is the exposure that creates a risk of 10^{-3}?	Potency, technical feasibility	Workplace air shall contain no more than Y ppm MC	• non-compliance • more toxic substitute • increase ventilation (but increase environmental exposures) • strip paint less often (accidents?)
What is the best available technology for paint stripping?	Control efficiency	Process stream must be directed into carbon adsorbers; workers must wear respirators	• comply (more accidents?) • bankruptcy? • relocate overseas?
How can we repaint planes at the minimum of [risk plus control cost]?	Risk, efficiency, cost, distributional effects	Steel shot, starch pellets, walnut shells, or the like must be used in favor of solvents	• comply at lower cost • waste disposal problem reduced
How can we provide air travel at the minimum of [risk plus control cost]?	Risk, efficiency, cost, distributional effects	Ban (tax) painted aircraft and/or subsidize unpainted ones	• coated metal with artwork • less fuel used*

*An unpainted Boeing 747 weighs 500 lbs. less than a painted one; American Airlines saves 7 million gallons of jet fuel per year (about 0.5% of its total fuel consumption) by eliminating paint, with concomitant benefits for air-toxics and greenhouse-gas emissions (Segelstein 2008).

and is easier to verify, but the degree of risk reduction (with or without considering offsetting risks) is not gauged.

The fourth row of Table 3 asks the most basic solution-focused question: what are the risks and costs of methods to fulfill the function? (The function is defined for the moment as "freshly-painted aircraft"). It is possible that mechanical removal of old paint, using more or less abrasive materials, could emerge as the method providing the greatest net benefit, and not incidentally one that defuses the potential zero-sum risk transfers (assuming there are no significant ergonomic risks to the workers handling the new spray guns).

The fifth row of Table 3 supposes that the agencies (perhaps joined here by their national counterpart energy and transportation agencies, who have a vested interest in fuel economy) choose to ask a more fundamental solution-focused question: could the function be fulfilled without the cycle of painting, stripping, inspecting, and repainting aircraft? American Airlines implemented its own "ideal final result" (Domb 1997) on its own accord some years ago, and now saves 7 million gallons of jet fuel per year by coating the bare metal rather than painting it. This is an example of "SFRA 2.0"—a solution to evaluate that comes from a willingness to expand the boundaries of acceptable corporate or public discourse.

There is no reason that government, industry, and the affected public could not convene and ask even more probing questions about the function of air travel: to the extent that some portion of it serves to bring people together for face-to-face meetings, aiding innovation in the sector that provides virtual substitutes for in-person meetings might generate still more net benefit by reducing energy use and the other externalities of air travel.

The "solution focused" question can be as ambitious as the participants desire: the point of this example, regardless of where the reader might begin to balk at the breadth of the solution, is that *no innovation beyond "less exposure to one substance (MC), to some of the affected persons" would be part of a decision process that defined the problem before considering the opportunities.*[11]

CONCLUSIONS

Risk assessment for its own sake is an inherently valuable activity but, at best, a risk assessment can illuminate what we should *fear*, and tap into our inexhaustible supply of worry— whereas a good solution-focused analysis can illuminate what we should do, and mobilize our precious supply of resources. In the same vein, the search for an acceptable level of risk is motivated by the noble desire to do less harm, but there is a different goal possible—to do more good. This latter orientation requires us to see opportunities where we are tempted to see only hazards to abate. I have never believed that risk assessment is or must be, in Montague's (1996) stark denunciation, the engine that "keeps the death camp trains running on time," but we need to be aware that there are alternative visions that take risk assessment out

[11]Similarly, defining the medical problem in the second entry of Table 1 as "uncomfortable pants" would foreclose thinking about diet and exercise (bigger pants being a cheap and effective solution to this problem so defined).

of the equation in the vain hope that deregulation, or precaution, or "best available technology" alone can make the choices facing us less tragic (Calabresi and Bobbitt 1978; Montague and Finkel 2007).

The notion that analysts and decision-makers must interact is no longer controversial. And others have moved the center of gravity of our field gradually toward the conclusion that decision options ("solutions") should be arrayed earlier and earlier in the process than the Red (or the "mis-read" (Mirer 2003)) Book originally intended. *Science and Decisions* (NRC 2009) is to date the culmination of this forward motion to turn risk assessors loose to evaluate solutions rather than hazards, and so this proposal for SFRA is incremental in that it moves the initial enumeration of possible solutions to the very beginning (after the signal of harm is deemed significant) rather than "closer to the beginning" as in *Science and Decisions*. It is much more than incremental, however, if I am correct that we will fail to see the situations we confront in risk management as both problems and opportunities unless we "formulate and scope" in a way that initially keeps some audacious opportunities open, until such time as analysis finds them to be impermissible or clearly dominated by other available responses.

But there may be something quietly revolutionary underway at USEPA, using *Science & Decisions* as a jumping-off point but emphasizing concepts similar to those presented here. While this article was being typeset, I came across an internal memo to the USEPA Office of Research and Development (ORD) staff from Paul Anastas, ORD's new chief (Anastas 2010). Anastas' memo "The Path Forward" quickly makes an unmistakable and elegant distinction between problems and solutions: "[u]nderstanding problems is important and essential; however, the only reason to deeply understand a problem is to empower its solution. A diagnosis alone is not a cure, and we must be in the business of facilitating solutions to the environmental problems we face." He then emphasizes the search for broad solutions, although as befits the head of a research operation, he couches it in terms of analytic breadth rather than inter-agency dialogue: "ORD will be fully engaged in Integrated Transdisciplinary Research, which is defined as the process to develop sustainable solutions to environmental problems by engaging partners who transcend traditional scientific disciplines throughout each stage of the research process." Anastas' memo never mentions the term "risk" or risk assessment; however, I have no doubt that the ORD staff, who collectively have pioneered human health risk assessment for decades, will interpret his vision in a way that defines an integral role for risk analysis in identifying the sustainable solutions the new USEPA leadership seeks. In my time in government, I saw many memoranda come and go, but I hope this one will get the attention and adherents it deserves.

I offer this proposal out of concern for human health and the environment, but also out of concern, misplaced or legitimate, for our shared profession of risk analysis. I look around at our unfinished risk-reduction business and believe that bolder solutions are worth contemplating, and that government—acting in concert with the regulated and the affected—must play a greater role in envisioning specific technologies and lifestyle changes than it has in the past. But I also look around and see others who share the sense of urgency about goals but who are contemptuous of risk analysis as a means. The marriage of technology options analysis and cost–benefit analysis proposed here is especially attractive, I believe, when viewed with eyes

open as an escape from technology-based interventions *without* risk analysis, or precaution without assessment, or exposure limits without considering whether too much or too little cost accompanies them. Perhaps a train is coming down the track wherein some new ways will be promoted for protecting human health and the environment—some wise, others less so, and still others counter-productive or worse. If so, we risk assessors should be on board that train, preferably in the lead car along with the conductor and the engineer, not watching it go by while we display our erudition and our understanding of hazards. And if that train is not already on the track, perhaps we risk assessors should put it there.

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Commentaries on Finkel Perspective Article

Comment on "Solution-Focused" Risk Assessment

Adam Finkel's article is a useful contribution to thinking about risk. Like almost all of Adam's writings, it is thought-provoking in the best sense of that term.

Although I have not talked with Adam about why he wrote the article, I suspect he is responding to the continual erosion of environmental health and safety regulation and the continual improvement and refinement in risk assessment methods. The two things are only remotely linked—the erosion of regulation is due primarily to a rightward shift in the political spectrum, the obsolescence of the legislative framework, and tectonic changes in campaign finances that have given regulated industries control over the political process.

That said, an examination of the risk assessment–risk management relationship is still of great importance. The relationship has never been simple or easy either in theory or practice. Even the Red Book (NRC 1983), which Adam cites as the source of the separation of risk assessment and risk management, is ambiguous (and perhaps ambivalent as well). Although the Red Book has an executive summary that strongly emphasizes the assessment–management separation, the main recommendation and large parts of the text say that the two neither can nor should be separated (see Davies 2003).

After several decades of experience and debate, there is now general agreement that risk assessment and management are and should be intermingled. As Adam notes, the process is "recursive"—"more information about risk refines the solution set and more information about solutions directs the analysis toward specific knowledge gaps and uncertainties." As he notes, "thinking about solutions should occur in parallel with thinking about problems."

Adam goes further, however. The core of his message is the importance of starting the interactive process with a focus on solutions rather than a focus on determining risk. Both risk analysis and cost–benefit analysis are necessary, but the analysis will be of limited utility or even counterproductive if it fails to start with the broader task of identifying potential risk-reducing solutions.

Can Adam's solution-focused paradigm help to make regulation more effective? I think that in many situations it can.

Solution-focused risk assessment aligns the interests and focus of the risk analysts much more closely with the interests and focus of decision-makers. Instead of pursuing separate agendas, the assessors and decision-makers would share a common interest in solutions. This would change the nature of risk assessment research and practice. New questions and techniques would arise. Instead of ever more exquisite

refinement of how to determine risk, the assessors would need to think about how to identify, frame, and analyze solutions. They would be engaged in a more robust and useful effort to solve problems instead of an academic effort to understand the risk of particular substances. Understanding the relevant risks is necessary, but we must ask whether the risk assessment is geared to the needs of decision-makers; does it get into the decision-making process in a useful and timely way; does it identify and clarify alternatives for action? Starting the process with the identification of solutions may often provide a positive answer to these questions.

Adam describes a process that necessarily involves complex interactions between risk assessors and risk managers. Any action aimed at reducing risk should take into account not only risk but also economics, law, and politics. If any of these are missing, the decision is likely to be faulty in some important respect. Adam focuses on the need to start with possible solutions, but, as he understands, the process is interactive, likely to extend over some period of time, and change with the nature of what is to be decided, the stage of decision-making, and even the temperaments of the players. Any decision of importance is in fact likely to be a series of decisions, and Adam highlights the importance of starting with solutions. The key to good decision-making is to properly orchestrate the many sub-decisions so that the end result is efficient, fair, and effective risk reduction. Adam's article potently reminds us of the importance of focusing on this final result and succeeds in delineating a way by which the decision process can be oriented to achieving it.

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The Cultures of Environmental Health Protection: Risk Assessment, Precautionary Principle, Public Health, and Sustainability

Adam Finkel makes us think. Reading his many writings is always an intellectual pleasure. I will take advantage of the Editor's request that commentaries use Finkel's article in this issue as a springboard. First, I will expand on my agreement with Finkel about the importance of problem identification. Using Finkel's writings as a base, I will briefly discuss what I believe to be cultural issues at the overlapping interfaces between risk assessment and the precautionary principle; and between public health and legal approaches to protecting the environment. By culture, I mean the sharing of attitudes and practices. I will end by advocating sustainability as a unifying approach to applying public health principles to environmental protection.

WHAT IS THE PROBLEM?

Finkel appropriately asserts that risk assessment should be "solution-focused." Certainly, this is preferable to, as he puts it: "letting the analysis of problems run wild and lead (at best) to knowledge rather than to action." As Finkel points out, solution-focused risk assessment (SFRA) obviously requires some understanding of the problem. The identification of problems and the consideration of options for solution is a reminder of the Framework for Risk Assessment and Risk Management (Presidential/Congressional Commission on Risk Assessment and Risk Management 1997). This six-step framework begins with Problems/Context and proceeds through Risks, Options, Decisions, Actions and Evaluations—all done iteratively and transparently, working closely with stakeholders.

I strongly agree that relatively too much effort is being expended on providing unnecessary detail about the problem as compared to using risk assessment tools to evaluate the solution to a specific problem; and suggest this is built into the culture of risk assessment. I recently took risk assessors to task for overusing risk assessment, even going so far as comparing ourselves to lawyers and surgeons who almost always seem to believe that more reliance on their professional skills is an answer to any problem (Goldstein 2010). As an example, the recent National Research Council report: "Science and Decisions: Advancing Risk Assessment" (NRC 2009), while in many ways excellent, is notable for the almost total absence of a problem statement—an absence it shares with many other academy and USEPA documents. What are the examples of how many human lives would have been saved, or ecosystems protected, if only the risk assessment would have been more accurately performed? Of course there are problems with risk assessment, and if we

followed the NRC recommendations we could improve our ability to assess risks. But to what end?

A problem statement is an almost universal starting point for a document containing a recommendation for action. The United States Declaration of Independence is one model. Its first paragraph states: "... a decent respect for the opinions of mankind that they should declare the causes. ... " Only at the end of the document, after detailing the many problems requiring redress, is there a paragraph describing the recommended action. Risk assessment, instead of being focused on the information needed to address a problem, too often builds on the opportunity provided by new science, such as molecular biology and computational toxicology. As a generalization, I suggest that the reason we are focused on knowledge rather than action is that our culture is primarily that of scientists who are somewhat removed from the goals and practice of environmental health.

ANOTHER CULTURAL ISSUE: THE PRECAUTIONARY PRINCIPLE AND/OR/VERSUS RISK ASSESSMENT

Exploring the relation of the precautionary principle to risk assessment provides another opportunity to discuss attitudes and practices. The field of risk analysis has perhaps the broadest range of core disciplines, as is exemplified by the membership of the Society for Risk Analysis (SRA). This breadth would seem to contradict my argument that we have a core culture that tends to differ with others involved in environmental issues. But I believe this point about our core culture can be demonstrated by exploring the literature about whether the precautionary principle is antithetical to risk assessment. The precautionary principle is broad and variously defined, and in some iterations has much in common with public health principles. Further, the precautionary principle is supported among those who consider themselves risk assessors, including myself, particularly for aspects such as burden-shifting and a focus on transparency and inclusiveness (Nusbaum *et al.* 2004). Further, there are precautionary approaches, such as conservative default assumptions, incorporated within risk assessment and many environmental laws are precautionary without being based specifically on the precautionary principal (Starr 2003; Hammitt *et al.* 2005; Goldstein and Carruth 2003).

The wide range of definitions of the precautionary principle has led to a distinction between those that are strong and weak. My bias is against the "strong" form for reasons that are particularly well expressed by Sunstein (2002). An example of the strong form of the precautionary principle is that resulting from the Wingspread meeting (Raffensberger and Tickner 1999). For example, the 1992 Rio Declaration, a "weak" form that gave impetus to the use of the precautionary principle, states that the threat of harm should be "serious or irreversible" and that the action should be "cost-effective," neither of which are found in the Wingspread statement. Further, Wingspread actively requires measures to be taken in the face of uncertainty while Rio more passively states that the lack of certainty should not postpone action (Goldstein 2005).

One of the most instructive readings about the strong form of the precautionary principle and risk assessment is a debate between Adam Finkel and Peter Montague,

a Wingspread participant who advocates the replacement of risk assessment by the precautionary principle (Finkel 2007; Montague 2007). They argue about the relative value of risk assessment and precaution over a range of specific issues, including asbestos control and the Gulf War.

Finkel defends risk assessment in part by going on the attack:

> The biggest challenge I have for you is a simple one: explain to me why "bad precaution" doesn't invalidate the precautionary principle, but why for 25 years you've been trashing risk assessment based on bad risk assessments! (Finkel 2007. in bold in the original)

Peter Montague is not alone among those who have been critical of risk assessment as part of an advocacy of the strong definition of the precautionary principle (Krimsky 1999; Raffensberger *et al.* 2000; O'Brien 2001). Of note is that none of the 30 signers of the Wingspread version of the Precautionary Principle appear to have been members of the SRA or the Society of Toxicology (Goldstein 2005). While the highly regarded signers are from a broad range of backgrounds, the voice in the Wingspread declaration is that of social scientists who are distrustful of science and scientists; it is the voice of deconstructionism and of post-normal science (O'Riordan and Rayner 1991; Funtowicz and Ravetz 1992). There are many social scientists within the SRA including many who have made outstanding contributions to the understanding and communication of risk. Despite inclusiveness being so central to those who advocate the Wingspread version of the precautionary principle, those who identify themselves with the field of risk analysis were not included among the participants in the Wingspread deliberations. This suggests a cultural barrier that fits in well with the definition of shared attitudes and practices.

I would add to Finkel's examples of "bad precaution" one that is particularly egregious, that of adding a ten-fold stringency to the EU aflatoxin standard in order to protect European agriculture. For a calculated decrease in liver cancer among 500 million EU residents of approximately one case every two years, this ten-fold more stringent standard excludes $700 million a year of trade from Sub-Saharan African nations, the poorest in the world, and is reputed to have negative environmental consequences (Majone 2002; Otsuki *et al.* 2001; Newing and Harrop 2000; Goldstein 2008). This and other EU protectionist trade decisions based on precaution are among the reasons for the failure of the Doha trade round, as developing countries question whether the EU would use the precautionary principle as a means to thwart any new trade liberalization rules.

LEGAL AND REGULATORY AND/OR/VERSUS PUBLIC HEALTH AND SUSTAINABILITY

Let me take this opportunity to correct the mischaracterization by Finkel and Montague of the removal of asbestos as being a failure of risk assessment. I was at EPA at the time, and did a simple risk assessment, later published in the context of exploring EPA as a public health agency, that supported the contention that a heedless rush to remove asbestos would produce more harm than good, and that had at least some impact on EPA's guidance (Goldstein 1988).

The asbestos in schools issue is also pertinent to another aspect of Finkel's commentary—the tension between the legal culture at EPA and EPA's public health and sustainability goals. As a generalization, the legal approach to the increase in risk posed by the headlong rush to remove asbestos was to establish rules to punish those guilty of malfeasance or incompetence. This enforcement approach moves the responsibility from the regulator to the public, In contradistinction, public health embodies the belief that the decision-maker is responsible for the outcome of the action. In my view, the current move toward sustainability, which in part encompasses Finkel's SFRA, is consistent with a public health culture that will not absolve the regulator from considering second order or generational impacts of regulatory action—or inaction. Public health is often contrasted with the treatment-oriented approach to ill people that characterizes most of clinical medicine. Similarly, sustainability can be contrasted with a legal "command and control" culture that has characterized much of EPA's activity to date. As a simplification, risk assessment plays the same role for regulatory command and control as do diagnostic approaches to curative medicine. Both risk assessment and clinical diagnosis depend on there being a problem that can be identified and quantified, while sustainability and public health primarily act to prevent the problem from occurring. Further, both public health and sustainability thrive in a culture of transdisciplinary systems thinking rather than reductionist science and practice. There is a mantra in public health that states that no significant public health problem can be solved by any one discipline acting alone. To focus on solutions, as Adam Finkel has asked us to do, requires that we recognize the cultural aspects of our disagreements, and focus on the shared attitudes and practices that unite our common goal.

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A Commentary on Dr. Finkel's Proposal for Solution-Focused Risk Assessment

I was asked by HERA's editors-in-chief to comment on whether Dr. Finkel's proposal for solution-focused risk assessment (perhaps "solution-focused risk management"?) would, if enacted, be superior to the current risk assessment/risk management paradigm. My initial reaction, not being a party to whatever discussions and controversies this proposal has undoubtedly already engendered, is that it points out some deficiencies in our current practice of risk assessment and risk management, particularly the tendency to analyze a problem rather than start moving to address it.

In the current paradigm, a problem (typically the negative consequence of a past decision) comes to light—the "signal of harm". Decision-makers are then faced with determining whether this problem, if not addressed in some way, could lead to, or continue to yield, negative consequences in the future. Similarly, if a new activity, process, or product is being proposed, decision-makers must consider (but how often do they?) whether it, if implemented, might eventually lead to negative consequences. In either instance, decision-makers and stakeholders must recognize (or anticipate) a problem and agree that it is (or could be) of sufficient significance to require a response (or a change in the proposal). At present, risk assessment (or more typically a conservative dichotomous hazard assessment) is the tool used to establish both the existence and the "strength" of the harm signal—decision-makers must then ponder whether it is strong enough to suggest the need for some action. Establishing the nature and extent of this signal (or even its very existence), particularly for high-profile problems, can be a very polarizing and paralyzing process, as extreme policy positions (*e.g.*, from no-action to the highly precautionary) may deny or magnify its existence, as well as manipulate, criticize, and impede the risk assessment, in hopes of furthering their differing, diverging agendas.

Dr. Finkel would have us proceed from signals of harm (as evidenced by "... adverse findings from one or more bioassays, epidemiological investigations, or observations of adverse ecological change ... ") to the sources of these signals, to identifying a wide range of alternatives (including no-action) to change these sources, and finally to a choice among alternatives based on overall risk (his Figure 1). As he points out: "Risks arise because sources of risk exist ... " Once a

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signal of harm is received and acknowledged, we would move directly to considering options to address this signal and would use risk assessment only to inform choices between options and not as the initial arbiter of whether a problem is worthy of concern. For each possible alternative (*i.e.*, decision option or solution), we would ask: "What is the probability that this alternative will lead to future increases in net social benefit?" Similarly, if we are making a proposal for some planned (new) activity, process, or product, we would ask: "What is the probability that this alternative will lead to unacceptable problems at some point in the future?

If our ultimate societal goal is actual risk reduction (or, perhaps, even its elimination in a few cases) and not just protracted rounds of analysis (with acid rain as a case in point (Likens 2010)), a framework that stresses doing something about an acknowledged problem sooner than later is, in my opinion, an attractive one. Too often, as Dr. Finkel points out, the problem continues on, perhaps for years, often inflicting more and more harm, while the debate over the meaning of the risk assessment goes back and forth, back and forth. His belief that "... (tentative) solutions should precede conceptually the detailed dissection of problems ... " may be seen as a legitimate reaction to the frustration of letting a recognized problem continue to fester while we analyze it *ad nauseam*. I am also in agreement with the expectation that decision-makers (risk managers) will be informed by the probability of costs and net environmental benefits, rather than of risk alone, when reaching decisions. A decision-maker given only an assessment of true risk (the probability of negative consequences associated with a give choice), as opposed to speculative risk (the probability of both the positive and negative consequences attendant to a given choice), is, in my opinion, not being given sufficient information to make an informed decision (Scholz and Siegrist 2010).

However, while considering solutions sooner than later has considerable merit, Dr. Finkel's proposal raises, from a purely practical perspective, a few questions.

(1) What if we cannot agree on a "signal of harm"? This to me is the key question. All of these frameworks (current (*e.g.*, USEPA 1998, 2003), National Research Council (NRC 2009), solution-focused) are initiated by some "signal of harm" and each pre-supposes that the existence and strength of this signal will be agreed on (eventually) by all concerned. As noted previously, the current and NRC frameworks use risk assessment to characterize this signal and to inform decision-makers (and stakeholders) of whether it is worthy of further attention. The solution-focused approach seems to make the unrealistically hopeful assumption that acknowledgment of the existence and strength of this signal can be taken for granted, and leaves unanswered legitimate questions about how such a signal would be characterized and by whom. While regulatory agencies are typically given wide latitude by the courts when defining a signal's existence and strength, even they cannot do so *ex cathedra* absent credible and defensible supporting evidence. From the regulated community's perspective, acknowledging such a signal could lead to a decision requiring a perhaps costly and difficult to implement action. If the entity toward which this decision is directed does not want to take that action, there will be an argument. Conversely, if a third-party feels the called-for action is insufficient or misdirected, there will be an argument. Everyone can support risk reduction, provided someone else has

to bear the burden of doing it and paying for it. So, risk assessment or not, arguments about a signal's existence and strength are going to be raised by various agendas, ranging from those who never see a worthy signal to those who see any number of them, all equally deserving of attention. With the solution-focused approach we could just be replacing arguments about risk assessment with those about whether there's a meaningful signal of harm or not.

(2) Is source identification and attribution that easy? All frameworks presume that a signal of harm has a source or sources. The solution-focused approach states that the "... risk manager is to go back to the source and ask how changing it can create a future with ... increases in net social benefit." While there is no argument that a source or sources must be addressed, it has been my experience, with air quality issues and Total Maximum Daily Loads, that the practical challenges of source identification and attribution are at least as great as those of obtaining agreement on the existence and significance of any signal of harm. The solution-focused approach appears to underestimate the possible complexities—from technical to legal—with respect to characterizing both a signal and its source or sources. Information to identify sources is not always already available and defensible source attribution may require time and resources to gather requisite data. Sources are rarely obvious and there is usually (often stiff) resistance on the part of a regulated entity to being identified as a source or, worse, as "the" source. I would therefore not expect arguments about sources to be any less likely or contentious as those about signals.

(3) Aren't we already supposed to be doing this? Dr. Finkel states that "... the key step that makes a decision process 'solution-focused'... " is one that "... requires a brief moratorium ... until risk managers and assessors [and presumably their constituents and stakeholders] discuss the following sorts of questions... " It is not clear to me how this "brief moratorium" differs in substance from the planning and problem formulation processes that are already supposed to be an integral part of existing human health (USEPA 2003) and ecological (USEPA 1998) risk assessment frameworks? The questions he outlines are exactly those for which answers would be expected if decision-makers actually fulfilled the intent of these "procedural" tasks, instead of allowing assessors to skip ahead to focus on the "scientific" algorithms, models, and toxicological minutia of risk assessment itself. I would like to believe that existing risk management frameworks, and certainly the one in NRC (2009), could be modified to a solution-focused approach if legitimate and robust planning and problem formulation activities were forced to occur, (b) if the outcome of these activities was used to identify options for possible immediate implementation, and (c) if risk assessment was then used to inform choices among longer-term or more complex options and not as the sole gatekeeper to whether any choice was necessary. In current frameworks, a risk assessment is posed as the inevitable consequence of commencing planning and problem formulation activities. Frameworks could be modified to make these activities much more closely associated with the decision context than with a risk assessment, thus making it possible to move from problem formulation (*i.e.*, acknowledging a signal of harm) to decisions (solutions) without first passing through a risk assessment. Such a change would recognize that a risk assessment is

not necessarily the only or best tool for informing decisions. It would also minimize having the ultimate objective of all this activity, the reduction or avoidance of future negative consequences, obscured by repetitive bouts of analysis.

(4) Is this approach really that different? The National Research Council (NRC) (Abt *et al*. 2010; NRC 2009) has put forth an updated risk assessment/risk management framework, one that "... focuses upfront on the options that are available to reduce hazards ... and on the structure of the risk assessments needed to evaluate the merits of the options being considered... " (Levy 2009, p. 5). I may be insensitive to some philosophical nuances here, but the differences between the NRC framework and the solution-focused alternative seem to be more a matter of emphasis and degree, than of substance, in that both start with signals of harm, consider options to address those signals, and use risk assessment to inform choices among these options. However, as noted before, neither can really proceed until there is some agreement among decision-makers and stakeholders that a signal of harm merits moving forward toward either a consideration of solutions or a risk assessment.

(5) Will this work if we only assess hazard and not risk? Dr. Finkel states that "... SFRA will demand more complete and rigorous analyses ... moving ... in favor of continuous relationships between exposure and consequence." While I fully agree with this statement, I question whether we yet have the political or regulatory will, managerial experience, or technical capacity to perform and interpret risk assessments that yield probabilities, as opposed to hazard assessments based on dichotomous benchmarks that give decision-makers essentially "yes/no" answers. Outside of sports scores, and certainly for most decision-making, a dichotomous threshold is a poor substitute for probabilities. A precautionary hazard assessment biased to minimize Type II errors irrespective of cost effectiveness is also of little help to decision-makers trying to balance the costs and benefits of various alternatives. However, while a few high-profile situations have used risk assessment to estimate probabilities, lesser (*i.e.*, the majority) situations (including major Superfund sites) have gotten, and continue to get, by with simple hazard assessments. If the solution-focused approach requires more rigorous risk analyses, can we do them on the scale demanded? This, based on my experience to date, remains an open question (Hope 2009).

Dr. Finkel's proposal for solution-focused risk assessment brings many provocative and challenging thoughts to the discussion of decision-making under uncertainty. The focus on net environmental benefits (speculative risk) is an important and necessary departure from our current true risk-only approach to informing regulatory decision-making. Nonetheless, it is hard to see the solution-focused approach as unilaterally superior to existing approaches. For one thing, its application is no more likely to avoid the contentious debates that currently befall the existing risk assessment framework or NRC (2009)—it just moves arguments about risk assessment and its meaning to no less challenging debates about "signals of harm" and their sources. While abandoning these frameworks in favor of a solution-focused one seems unlikely, it may be entirely possible, and beneficial, to seriously consider accommodating aspects of his proposal within these existing frameworks. Regardless,

the real impediment to the expeditious reduction or avoidance of risk is probably not the framework we chose to follow—be it the current one, NRC (2009), or solution-focused—but simply our cultural (and legal) propensity to argue and dispute when profits or our comforts are threatened or the potential for increased costs is in play.

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Making Credible Scientific Judgments about Important Health and Ecological Risks and Ways to Efficiently Reduce Those Risks

INTRODUCTION

During the past 40 years, risk assessment has emerged as an organized, systematic, scientific activity closely tied to important questions about the nature, magnitude, mitigation, and prevention of health and environmental hazards. A significant starting point was the 1977 report from the Environmental Protection Agency (Albert *et al.* 1977). We have long recognized that risk assessment embraces identification, characterization, and means of reduction of risks, not just quantitative estimates of risk and uncertainties. Moreover, risk estimates should not claim patently false precision (like 2.34×10^{-5} lifetime risk). In fact, from the early days, we urged that the term "risk characterization" be used to overcome the common assumption that risk assessment was synonymous with quantitative risk assessment; characterization includes presenting biologically and clinically useful descriptions of the adverse health effects and their potential reversibility (Calkins *et al.* 1980; NRC 1983).

We have long recognized that the primary consumers and often the primary sponsors of risk assessments are the federal regulatory agencies, including the U.S. Environmental Protection Agency (USEPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), U.S. Department of Agriculture (USDA/Food Safety and Inspection Service [FSIS]), and Nuclear Regulatory Commission (NRC), and their state counterparts, whose policy orientations can shift remarkably with change of administration following elections.

My comments are formed by academic experience at the University of Washington and the Fred Hutchinson Cancer Research Center, creating a risk assessment focus in the Department of Environmental Health, and leading the beta-Carotene and Retinol Efficacy Trial (CARET) for lung cancer chemoprevention in smokers, former smokers, and asbestos-exposed workers; by government roles as deputy science adviser and OMB associate director in the Carter Administration, plus various advisory boards, including the USEPA Science Advisory Board and Clean Air Scientific Advisory Committee; by service for the National Academy of Sciences/National Research Council on numerous study committees and the Report Review Committee, chairing the Board on Environmental Studies and Toxicology and the Committee on Science, Engineering, and Public Policy; by service on the Environmental Advisory Council and Board of Directors of the Rohm & Haas Company; and by chairing the Presidential/Congressional Commission on Risk Assessment and Risk

Management during 1994–1997. I served, together with other notable colleagues, on the National Research Council committee that produced the influential 1983 "Red Book" on "Risk Assessment in the Federal Government: Managing the Process (NRC 1983)," and contributed to the HERA anniversary volume for the Red Book in 2003 (Omenn 2003).

THE CHARGE AND THE BACKGROUND

Editor Barry Johnson has invited commentaries about the state of risk assessment in the context of the manuscript from Adam Finkel. This article reopens one of the many questions addressed in the Red Book. The Red Book Committee examined several existing arrangements for agency-specific allocation of responsibilities for risk assessment and for risk management. At one end of the spectrum then and still today was the combination of National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA), agencies in different Cabinet departments with clear separation of the research (and risk assessment) function in NIOSH and the worker protection risk management responsibility in OSHA. Subsequently, NIOSH became a subagency of the Centers for Disease Control and Prevention (CDC), which provides useful scientific and disease prevention/health promotion context. OSHA operates under one of the most difficult laws for management of health risks, with language requiring that health standards be set such that "no worker, even if exposed at the maximal permissible level for a full working lifetime, shall suffer any adverse effect." Such absolute assurance, in the face of individual genetic and behavioral variation, has been difficult for OSHA administrators, scientists, and advisers to act upon. Another agency with risk assessment separated from risk management is the Consumer Product Safety Commission, which depends on advisers proposed by the National Academy of Sciences and their independent advice, with a scientific coordinator on staff. In the middle is the USEPA, whose assistant administrators implement statutes peculiar to each environmental medium (air, water, drinking water, solid waste, hazardous waste), rather than an organic statute for the whole agency; each has wide discretion whether to draw on the USEPA Scientific Advisory Board (SAB) and/or program-specific advisory groups. In practice, the Clean Air Scientific Advisory Committee (CASAC) has been quite influential about Clean Air Act standard-setting and has established a rather independent position. Given the periodic reviews of incremental scientific knowledge about Criteria Air Pollutants (section 109) and tight linking of risk management options with such risk assessments, USEPA has long performed what Finkel calls "solution-focused risk assessments." Of course, the implementation of national ambient air quality standards (NAAQS) rests with the states, with oversight by USEPA. The SAB has established ties to the administrator of the agency. Congressional intervention and industry pressure has been most severe for the USEPA. Finally, the Food and Drug Administration (FDA) and its various technology-based program divisions have risk assessment intimately integrated with the regulatory functions, mediated through staff analyses and advisory panels on policies and on new product submissions.

Sensitive to the pressures from top agency officials and top Administration officials to obtain scientific support for proposed policy positions, the Red Book

Committee strongly supported separation of risk assessment and risk management functions either within an agency or through cooperating different agencies. At the same time, the Committee urged that risk assessors and their advisers be well-informed about the statutes, the relevant past decisions, and the potential risk management strategies. Finally, the Committee reinforced the lesson that risk management decisions are not adequately framed with only scientific opinions; there are legitimate technological, social, ethical, economic, and political dimensions for choices among risk management options.

A critical element of regulatory practice is the recurring examination of particular risk management challenges. As Judge David Bazelon, highly esteemed Chief Judge for 31 years of the Federal District Court for Washington, DC (hence for most regulatory agencies) said in a 1979 lecture at the University of Southern California on "The Perils of Wizardry," scientists need to respect the limits of their special expertise. He counseled that scientific opinions should be clearly divided into three domains: what is known and accepted, and might be stipulated by both sides of a dispute; what is known but disputed, which might be clarified by further evidence; and what is not known or even not measurable at present, which might be informed by future discoveries and methods. His advice drew on the experience that important issues tended to recur over time, which makes a coherent and clear record all the more valuable. For a solutions-focused approach, it is important to acknowledge that decision-makers rarely start from scratch with a never-before-recognized problem; thus, even an independent risk assessment should, and generally does, begin with current and proposed solutions, like NAAQS or FDA food contaminant thresholds or drinking water maximal contaminant levels (MCLs).

For the Bazelon approach, one of the most important developments of the past 30–40 years has been the investment in measurements of exposure and body burden, overcoming a practice of relying on assumptions and hypothetical models. Measurement of individual variability in susceptibility remains an underdeveloped feature. Improvements in exposure and susceptibility data could make risk assessments of both problems and solutions more reliable.

THE FINKEL THESIS

The opening statement in the original Abstract was a surprising premise: "More attention and resources have been expended on dissecting problems than on implementing actual solutions that reduce risks." No estimates were given in the text. I do not recognize the process of "risk assessment for its own sake." Implementing actual solutions is the responsibility of the polluters for emissions and employers for workers. The billions in expenditures for emission controls alone far dwarf the millions spent on risk assessments. No doubt the author refers only to the activities of agency regulatory personnel. The second sentence was also incorrect: "The basic dogma since the 1983 National Research Council's 'Red Book' (NRC 1983) is that risk assessment must precede risk management (risk management should not begin until the problem is fully understood)." Instead, as noted above, the Red Book Committee clearly addressed integration and interaction between risk assessment and risk management, while respecting their different domains and driving principles.

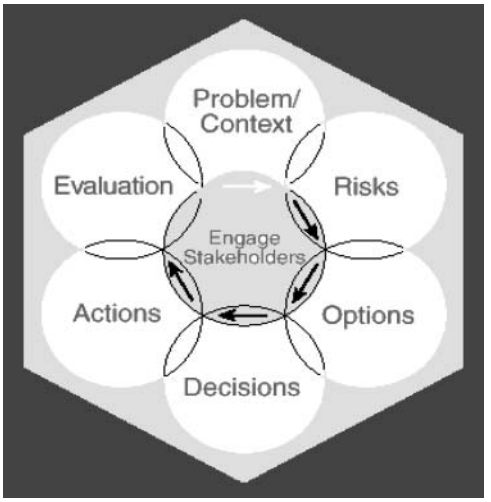

Figure 1. The Risk Commission's Six-Stage Framework for Risk Assessment and Risk Management. The critical role of stakeholders in setting the context and guiding technical assessments is indicated by the larger ellipse in stage one. The arrow is removed from stage six so as not to encourage "paralysis by analysis".

The Presidential/Congressional Commission on Risk Assessment and Risk Management presented a "framework for risk management decision-making" that has been widely adopted: starting with "putting the problem in context" before launching into risk assessment, and actively engaging stakeholders from the start, not after the solutions have been determined by government officials. The framework is shown in Figure 1 (Omenn 1996; Presidential/Congressional Commission 1997). The hexagon also reflects the iterative nature of risk management, with inputs from risk assessment both before and after any set of risk management options has been proposed, declared, evaluated, and then considered again in due time.

Finkel correctly emphasizes the need for risk-risk analyses of proposed risk management actions and the need to put new data, new concerns, and new or differently utilized technologies into broad context. Context was a major theme of the Risk Commission report—examining all sources and pathways of exposures to a particular hazard or class of hazards, on the one hand, and considering all known or suspected causes of adverse health or ecological effects to estimate the relative contribution of any particular cause, including the one under regulatory review. Thus, risk assessment for the management options themselves, the "solutions," to identify the introduction or increase of hazards other than the one targeted to be reduced, is certainly a good idea.

Finkel does insist that the risk management process must begin "after the signal of harm is deemed significant." That leaves quite a potential range of effort, surely to be based on the evidence or limitations of evidence, to make that judgment. Good management of risk assessment allocates human resources and time according to the importance of the questions, problems, and solutions; it is insulting to propose that maximal, if not endless, analysis characterizes every regulatory agency or academic

risk assessment. This point should remind us of the salient title of the "Science and Judgment in Risk Assessment" report from the National Research Council in 1994 (mandated, as was the Risk Commission, by the Clean Air Amendments of 1990). Also, we should consider "value of information" models, such as one economist Lester Lave and I proposed years ago to determine how much effort could be justified under various scenarios for testing of chemicals for carcinogenicity, including the relative values placed on false-negatives and false-positives (Lave and Omenn 1986). We should note that making a decision or offering alternatives for a potential action or "solution" in the form of a regulatory agency standard is hardly the same as achieving the intended reduction of risk or observable adverse effects.

An idealization of government action is the call for cross-agency integration of risk management solutions for complex problems. In fact, there have been highly productive multi-agency processes, some stimulated in the Carter Administration by the Interagency Regulatory Liaison Group (ILRG), comprising the heads of USEPA, FDA, OSHA, and CPSC (and later USDA/FSIS), with close ties to the White House Office of Science and Technology Policy. Good examples were formaldehyde and lead and possibly diesel exhaust.

In 1983, USEPA Administrator Bill Ruckelshaus wrote in *Science* that "Current statutory mandates designed to protect public health both demand levels of protection that technology cannot achieve and are uncoordinated across government agencies. A common statutory framework for dealing with environmental risks is needed. In addition, care must be taken to separate the scientific process of assessing risk from the use of such assessments, together with economic and policy considerations, in the management of risks through regulatory action."

Given the lack of an "organic statute," USEPA often has struggled to deal with a particular chemical hazard across various offices. Part of the problem is statutory, given different policy approaches and different regulatory regimes for different media. Part of the problem lies in failure of the scientific community to study what, in retrospect, seem like obvious risk-risk situations. I have in mind the Congressionally mandated introduction of methyl-tert-butyl-ethanol (MTBE) as a fuel additive to reduce criteria air pollutant emissions; the fact that MTBE soon contaminated water supplies should have been anticipated from knowledge of "the water cycle," a standard elementary school science project. If we aim to reach across agencies, we might alert ourselves to identify combined risks from infectious agents and chemical exposures in the occupational, medical care, and general environments, including risks to healthcare workers.

The Risk Commission framework called for putting hazards and exposures in context before charging off to battle with just one potential cause of, say, birth defects or lung cancers. This guidance matches rather well the Finkel recommendation for fresh thinking about what solutions might be cost-effective and risk-reducing, whether the surface protection of airplanes or a host of other needs. And I agree with his statement that there can be a "logical marriage of the risk-based and technology-based ways of thinking—namely, a risk-based technology options analysis." Boer (2002) has proposed such an options analysis for portfolio-style investments in R&D; the same could apply to the world of regulation-driven investments by society overall or by particular economic sectors.

I do not understand the objection to risk-based and exposure-based goals. Nor do I agree with the attack on "bright lines." As discussed carefully in the Risk Commission report, bright lines are risk management solutions for a practical world, where decisions are required about compliance, or not, with standards or for release, or destruction, of crops like aflatoxin-contaminated peanuts or corn. Moreover, the example of successive dioxin risk assessments is much less a problem with the risk assessment process than a prime example of risk management decisions to delay issuing a controversial rule!

THE POLITICAL CONTEXT

It is no secret that there are periodic shifts in political philosophy, especially about health and safety regulation, following national elections for president and for Congress. The same occurs at the state level. The range of solutions deemed relevant by a particular agency, let alone the Executive Branch leadership, may change drastically, as with "The Contract with America" in 1995 and several dramatic swings of the pendulum since then. Building a record of scientific evidence about toxicity and exposures, about performance of technologies in various applications, and about accompanying behavioral changes is a worthy goal over the long term. To the extent that respect for the scientific method and for challenges to scientific conclusions at any point in time can be sustained, the entire health and environment agenda of the nation may benefit. In other situations, the statutes themselves may need to be updated, as has happened periodically with the Clean Air Act. After watching USEPA struggle with an infeasible mandate under Sections 111 and 112 for "hazardous air pollutants" to generate a limit on ambient levels that would have no adverse effects (zero exposure) and do so with an "ample" margin of safety (a negative value, a greater margin of safety than the "adequate" margin for criteria air pollutants), Congress finally introduced in 1990 technology-based standards with a later review (now underway) of residual risks. Congress did not correct the rhetoric, but did lay a practical process on top of it.

Finkel's call for precise analyses of "net social benefit" from complex interventions, way behind the expected purview of a particular regulatory agency, triggers thoughts of proposing solutions for economic and environmental sustainability, national security, and other grand challenges!

I agree also with his support for risk communication and public engagement. He mentions the "Tacoma Process" for proposed tightening of emission controls at the Tacoma, Washington, copper smelter. Newly returned to be USEPA administrator, Ruckelshaus chose to put the spotlight on this decision. I was, in fact, the moderator of the first of the three workshops, held in Vashon Island just across Puget Sound from the smelter, a place known locally as "Walden Pond West." The residents were quite chagrined that the prevailing winds brought industrial effluents to their pristine island. Two assistant administrators of USEPA, a group of USEPA risk assessors, and all three national TV channels were there; after the risk assessors gave a nearly incomprehensible technical presentation, the residents asked many reasonable questions for which no one was prepared, relating primarily to hazards

for their children and their pets. The *New York Times*, regrettably, slammed the whole process as the USEPA administrator forcing his responsibility on the local citizens.

CONCLUDING REMARKS

Utilizing risk assessment for proposed solutions is a fine application of our methods. Drawing a wide net around the potentially relevant aspects of an environmental health problem, whether a single chemical, or the Gulf of Mexico oil, or the progress of global climate change, and seeking really effective and cost-effective solutions is a good aim. Ridiculing risk assessment—"letting the analysis of problems run wild and lead (at best) to knowledge rather than to action"—is not a necessary step to utilizing risk assessment in many situations. The level of effort should be pegged to the issues at hand and the simplicity or complexity of the questions to be addressed both to evaluate and characterize the hazards and to guide the solutions.

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Comments on Dr. Finkel's Paper on Solution Focused Risk Assessment (SFRA)

In this issue of the journal, Dr. Adam Finkel presents his proposal that it is time for risk assessments to be prepared or used in a different manner. Specifically, he notes that "more attention and resources have been expended on dissecting problems than on implementing actual solutions that reduce risks." He follows this thought by suggesting that those of us in the risk assessment community adopt a new term or approach called "solution focused risk assessment" (SFRA).

Dr. Finkel is no stranger to the field of risk assessment and is well respected (Paustenbach 1989a,b). He has made many contributions over the years, and he has challenged many of us to reflect on the way the field is practiced and how data should be interpreted. More than most other scientists, he has questioned whether the confidence that some of us have in the process and its results are warranted. This questioning has, in my view, raised the quality of assessments conducted over the past 20 years. Thus, I believe all of us should give consideration to his proposal.

For my part, I have tried to stay abreast of both the theory and practice of risk assessment since the day I was asked to review the NAS Red Book in 1982 (NRC 1983). Since then, my colleagues and I have probably conducted more than 1,000 assessments of chemicals or radionuclides in contaminated soil, sediments, air, water, and a host of consumer products (Paustenbach 1989a,b; 2002). As I read Adam's article, and I have read it several times, I tried to understand how his ideas would change the daily practice of our field.

The premise of Dr. Finkel's proposal is that we should move from having risk assessments identify not problems, but, rather, decisions. He indicates that scientists and decision makers have been incorrect in believing that "you cannot think about solutions before you fully understand the problems." He proposes that scientists "must change the timing of when risk assessors consider risk management solutions, and may change the nature of the solutions considered." He suggests that it would be better if "alternative risk management pathways are arrayed before scientific analyses of exposures, potencies, and risks begin ... in order that these analyses can focus on the risks (and costs) of specific actions."

I believe that Dr. Finkel has again challenged us by offering a novel suggestion that may have merit, especially in certain situations in which a genuine problem not only exists, but where the majority of scientists or regulators believe that it also deserves to be remedied in a timely fashion. The following are a few views that I hope will offer insight from the perspective of someone who has had the privilege of working in the field nearly every day for 30 years.

a. Dr. Finkel's proposal to go directly to "focus on possible solutions" to a perceived a real problem as a first step has some appeal. Surely, there are some risks which can be reduced rather quickly without significant effects on the economy and which simply "make sense". Sometimes, there will be times when a substitute for the chemical can be made easily and the substitute clearly poses less of a hazard to humans or the environment. At that point, one would need to address any legal challenges regarding "due process" and the decision maker would need to be certain that the perceived "obvious" substitute did indeed lessen the overall hazard. Sadly, we have not always done that well.
b. Dr. Finkel's assertion that the "traditional process can end with no risk-reduction actions at all" is accurate and, I would suggest that this is not necessarily bad. One sense that I have about his proposal is that he believes that anything that requires a risk assessment also requires a solution; that may sometimes be the case, but, often, it is indeed a useful outcome if a risk assessment concludes that the risk is trivial. Indeed, as time passes, we will more frequently conclude that this is the case as we continue to lessen or eliminate the significant risks. As such, one modification to the SFRA approach that I would recommend is that it be applied only after a screening assessment concludes that the risk is worthy of additional analyses. I believe that the proper application of the current scheme is more than adequate for doing just that.
c. I recognize that Adam's current view is that we should, in virtually all cases, tackle the assessment of any public health risk by immediately searching for solutions. I respect that view but, frankly, do not know how to implement such an approach in a practical manner. I do believe that experts can often intuitively screen out or "move to the back burner" those risks that are not worthy of consideration at this time. For example, I would not have experts invest the time evaluating the risks and then documenting deliberations if they were asked to assess the hazards of paints containing 10% mineral spirits but, I can certainly envision having an expert panel adopt an SFRA approach and skip the step of conducting a $1M classic risk assessment to quantify the hazards of disposing of nickel-cadmium disposable batteries into municipal land fills.
d. Along these same lines, throughout the paper, the reader gets the distinct impression that most risks that we encounter (especially exposure to so-called industrial chemicals) deserve to be reduced. Perhaps Dr. Finkel did not intend to give this impression, but many segments of society do have this mindset, and I believe this kind of thinking produces decisions that are often counterproductive to the improvement of the quality of life (and, often, life expectancy) (Foster *et al*. 1993; Kabat 2008). As the Supreme Court indicated in its benzene decision of many years ago, regulatory action should usually occur only when there is a clear indication that when exposure is reduced, there will be a measurable lessening of the risk to the consumer or worker. Recent pressures from various NGOs continue to emphasize that "less is always better," and this idea is well exemplified in the recent media frenzy over the alleged measurement of hexavalent chromium in the drinking water of hundreds of municipal water districts. In my view, the EPA and others should have immediately noted that the concentration of the hexavalent chromium is what is actually important, not just the fact that the chemical itself was measurable. And, secondly, the appropriate

agencies should have noted that, at low concentrations, the stomach readily converts Cr VI to the harmless Cr III, which is virtually non-toxic (indeed, most persons are chromium deficient). Note, however, that I am not advocating that persons be intentionally exposed to excessive concentrations of Cr VI nor do I have a strong view if society chooses to install equipment to minimize chromium or any other substance from drinking water

e. On a macro basis, I do find the SFRA approach to be an attractive one for those risks that are generally accepted to be worthy of the effort to reduce or eliminate exposure. I agree with Dr. Finkel that for much of the past 30 years, a lot of time and effort have been expended arguing about whether the optimal approach has been selected for conducting a quantitative estimate of risk, when, generally, most persons would agree that it would be worthwhile to reduce exposure to that particular chemical (even if the precise risk reduction with decreasing dose is not fully understood). Numerous examples come to mind, but perhaps there has been no better case study than that of dioxin.
f. I am not sure that the risk management approach to dioxins/furans embraced by the Nordic countries many years ago would fit under the definition of SFRA, but that approach certainly changed my view about how a nation can efficiently reduce exposures to a chemical that probably deserved attention without having to fight, as we have in the United States for 35 years, about whether we fully understood the qualitative risks or quantitative nature of the dose–response relationship (for whichever adverse effect you believe exists) of that chemical.
g. Specifically, back in the late 1980s, when the concern about dioxin emissions from combustors/incinerators was at its peak, there was a flurry of reports that dioxins/furans caused several different kinds of cancer, endometriosis, birth defects, memory loss, diabetes, and so on. Over time, nearly all of these claims were called into question by various epidemiology studies, or their underpinnings were found to be fatally flawed; many continue to be intensely debated. However, when the Nordic countries concluded that this family of chemicals was very persistent in the environment, and that they likely didn't have any beneficial effects at low doses, instead of arguing for years about the quality of the risk assessment, or having the regulatory decisions tied up in the courts, the various parties reached agreement on a program that required gradual emission reduction, over a fairly long period of time (about 20 years). These countries hoped that the reduction goal would be achieved without a rapid dramatic impact on commerce or productivity in the short or mid-term, but that end result would be favorable and, at the same time, avoid spending tens of millions of dollars in scientific research, assessment, and litigation. From what I can determine, the approach was successful.
h. Also, at the big picture level, I like the idea of gathering together bright, dedicated, and focused thinkers to identify possible solutions to a perceived or real problem (or risk) before going down the road of conducting numerous toxicology or epidemiology studies or a thorough risk assessment. Sometimes, it will be readily apparent that there is a cost sensitive solution that can quickly be implemented. Other times, though, a rather short list of likely "best solutions" can be identified, and then a risk assessment, risk-risk tradeoff analysis, or cost–benefit analysis can be conducted on these various possibilities. The current debate

about nanoparticles, such as carbon nanotubes, might benefit from this kind of evaluation.

i. As noted previously, I do believe that some emphasis should be placed on the importance of conducting a screening analysis to determine if the perceived risk is genuine. This task, of course, might be an insurmountable problem for certain chemicals or risk categories; especially those for which there is a visceral contempt for the alleged plausible hazard For example, to this day, there continues to be intense disagreement about whether some chemicals, especially at the low concentrations found in the environment, genuinely pose an endocrine disruptor hazard to humans. It is unclear to me whether the questions surrounding endocrine disruptors or other controversial issues represent a good or bad application of the solution-focused paradigm. One thing is for sure, however; at the extremes, this issue could have a dramatic impact on the economic well-being of many corporations, municipalities, and the federal government. I believe the recent concerns about pharmaceuticals, personal- care products, and related chemicals in effluents (and potentially drinking water) pose an equally difficult challenge to the risk assessment community and regulatory agencies.

j. I do embrace the view that it is important to make "risk-risk tradeoffs" front and center early in the process of evaluating risks. And, I agree that decision-makers deserve to be presented with this information (along with any other related scientific issues) quickly, so that they can decide whether resources should be expended to fine tune the magnitude of the problem, or whether to move forward in identifying the host of possible solutions that would inevitably be needed after a careful quantitative assessment was performed.

k. I also agree that, to the extent that SFRA will make more transparent the uncertainties in our estimates of risk, such increased transparency would be very good for both society and its elected officials. How this transparency might occur is not entirely clear to me, though, even after reading Dr. Finkel's discussion of this issue.

l. I read and understood the "counter arguments" put forward by various critics of the SFRA approach. Of the eleven arguments against adopting SFRA or some variation of it, I found none of them to be a "deal breaker." Indeed, for certain risks, like the phase-out of lead in gasoline and paints, the SFRA approach (in hindsight) would surely have been more productive than decades of arguments about the hazards of lead and our search for the true dose-response curve for lead's adverse effects at various blood levels. I see this decision to be very similar to the one adopted for dioxin by the Nordic countries. In fact, risk managers deserve to understand early in the process that "some action is inevitable" because the risks are simply of too great a concern to the public (even if there is a large uncertainty within the scientific community about the magnitude of the hazard). For those hopefully rare situations, an SFRA approach should be welcomed by risk decision- makers.

m. It is worth noting that, at some point in the solution focused approach, there will be significant pressure to conduct an economic analyses. My hope would be that these would be executed in a sober and transparent manner. Our profession has been plagued over the years by claims by Agencies that it is "not very expensive for the regulated party to comply with the proposed solution" while

> the group being regulated inevitably concludes tht "the impact on their industry would be catastrophic", In fact, experience has told us that quite often, the costs of implementation are significantly less that anticipated and that unanticipated benefits sometimes make the change an economically positive one due to efficiencies associated with adopting new production machinery of computer optimization.

Having been involved in many of the major risk assessment debates over the past 30 years (Paustenbach *et al.* 1990), I do believe too much effort has been expended at trying to precisely identify the likely best estimate of the exposure risk at particular doses of chemicals, rather than simply placing the various risks into one of three boxes and then making decisions about what actions to take. To be specific, proposals that embrace placing all of the various risk into category I (clearly worthy of continual reductions in exposure), category II (possibly worthy of attention but not necessarily immediate), and category III (based on current knowledge, the risk appears de minimus) have increasing appeal. For those risks placed into category I, the SFRA approach seems to have merit. For those same risks, I can envision that proposals for a gradual emission or exposure reduction, using a systematic approach over time, would be a reasonable solution (as with aerial emissions of dioxin in the Nordic countries). It seems to me that although the number of chemicals or risks that will be placed in category I have been dropping fairly rapidly over the past 20 years, there are still enough to keep us busy in the near term.

If the interested parties who have chemicals or risk scenarios in Category II wish to pursue research because they believe the risks are more fairly placed in Category III, there would be ample time for that work to be performed while the SFRA approach is applied to those in Category I. Indeed, classic risk assessment, as it is now practiced, should remain quite useful for characterizing these risks.

Although I remain a huge supporter of classic risk assessment, since it is far better than the "black and white" approach to dealing with risk that we embraced in the 1960s and 1970s, it might well be time to modify our thinking about the most efficient way to help inform decision-makers and the general public about how to lessen the various real or perceived risks to chemicals that are part of our daily lives. I remember vividly the early and mid 1970s, when the "carcinogen of the month" was reported in the headlines of every newspaper when the results of various animal bioassays were announced. Dose was not the issue and most persons believed that it was industrial chemicals that were causing cancer (until, of course, the famous study by Peto and Doll (1981) worked its way into the media). Also, few newspaper reports were sensitive to understanding the size of the potentially exposed populations and how any particular hazard ranked against any other. Later, when the Ames test was popularized, the same chemical demonization occurred on a routine basis, often paralyzing researchers and various industries from progressing with the development of new and exciting technologies or life-saving drugs. Risk communication is generally much better now than it was 20–30 years ago and it is clear to me that the "traditional risk assessment approach" (versus simply noting that a chemical is a carcinogen or developmental toxin) has generally served us well.

During the early years of risk assessment, it was not uncommon for scientists from the regulatory agencies to sit down at the same table with toxicologists/risk assessors

from industry, as well as the NGOs and their lawyers, to attempt to hammer out approaches to quantifying risk, reducing risk, or writing an appropriate regulation. For more than a decade, however, the increasing polarization between these three groups, often now including the academic community, has made it very difficult to move risk reduction forward in a productive and efficient manner (Fagin and Lavelle 1999; Michaels 2008). In large measure, the science has been squeezed out of the risk reduction or decision making process, and, instead, has given way to lawyers or those who can get the press to embrace their side of the argument (Morriss *et al*. 1999). My mind is therefore open to attempts to more efficiently identify and reduce the genuine risks to human health and, conversely, to identify those that are trivial so that we can devote our resources to other matters.

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