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Risk and Systems Theory

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The last few decades have seen increasingly widespread use of risk assessment and management techniques as aids in making complex decisions. However, despite the progress that has been made in risk science, there still remain numerous examples of risk-based decisions and conclusions that have caused great controversy. In particular, there is a great deal of debate surrounding risk assessment: the role of values and ethics and other extra-scientific factors, the efficacy of quantitative versus qualitative analysis, and the role of uncertainty and incomplete information. Many of the epistemological and methodological issues confronting risk assessment have been explored in general systems theory, where techniques exist to manage such issues. However, the use of systems theory and systems analysis tools is still not widespread in risk management. This article builds on the Alachlor risk assessment case study of Brunk, Haworth, and Lee to present a systems-based view of the risk assessment process. The details of the case study are reviewed and the authors' original conclusions regarding the effects of extra-scientific factors on risk assessment are discussed. Concepts from systems theory are introduced to provide a mechanism with which to illustrate these extra-scientific effects. The role of a systems study within a risk assessment is explained, resulting in an improved view of the problem formulation process. The consequences regarding the definition of risk and its role in decision making are then explored.

KEY WORDS: Risk assessment; systems theory; decision making; Alachlor

1. INTRODUCTION

The last few decades have seen increasingly widespread use of risk assessment and management techniques as aids in making complex decisions. However, despite the progress that has been made in risk science, there still remain numerous examples of risk-based decisions and conclusions that have caused great controversy.(1–5) The fact that journals devoted to the study of risk continue to publish papers arguing about the actual definition of risk indicates the level of controversy that exists at the operational level. Not surprisingly, severe disagreements are most common when dealing with the more complex cases: problems that involve multiple stakeholders, great uncertainties, and high stakes. Traditional risk assessment and management approaches have not fared well in handling these multidisciplinary, multidomain situations.(6–8)

We believe that many cases of disagreement or controversy around risk-based decisions and risk assessments can be traced to implicit and undocumented value-based decisions that affected the risk assessment, in particular during the initial formulation of the risk problem. Most structured risk assessment methodologies specifically define a "problem formulation" or similarly named step early in the risk assessment process, the purpose of which is to analyze and capture the scope of what is being studied and what exactly is being sought.(3,5,9–12) As with any

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other project or endeavor, the importance of the problem formulation step is paramount, as the quality of work at the outset will impact both the quality and validity of the results that follow. Implicit or undocumented assumptions and ambiguities in the initial problem formulation can seriously impact the value of even the most thorough risk assessment, as they allow the entire process to be questioned and second-guessed. Any improvement in the techniques that risk managers use to analyze, clarify, and communicate exactly what they are doing, both when formulating the risk problem and while working through to a solution, would be of value.

We contend that much improvement can be gained simply by leveraging the underlying conceptual roots of risk assessment, namely, systems theory and systems analysis.(13–15) Most seminal works on risk assessment acknowledge the importance of systems concepts, particularly in the problem formulation stage.(2,3,9–11) However, the use of systems techniques throughout the risk assessment process is rarely described explicitly, with the result that the lessons are sometimes lost. This article will demonstrate how explicit application of systems analysis concepts to the problem formulation stage of risk assessment can clarify many controversies and thereby assist in their resolution. The resulting approach to risk assessment applies to both complex, qualitative issues and to tightly scoped technical problems. The intent is not to produce a vast and completely new theory of risk based on systems theory, but simply to make explicit the concepts already present. It is hoped that the process and perspective presented here will assist in clarifying the roots of some disagreements over risk and provide an overall paradigm to assess contentious issues in risk analysis.

We begin by examining a risk decision of some notoriety in Canada, namely the Alachlor herbicide controversy as presented by Brunk, Haworth, and Lee.(6) Using this example, we illustrate how extra-scientific factors contributed to three different parties producing three different, and contentious, results. Concepts from systems theory are introduced to help model how these nonscientific factors affect the risk assessment process. This prompts a discussion of the critical yet often implicit step of system identification as part of the initial problem formulation of a risk assessment. The main lessons to be learned from this case study are discussed and several new ideas concerning the definition and role of risk are presented.

2. SOURCES OF CONTROVERSY

In the 1980s in Canada questions were raised concerning the health risks of the popular herbicide Alachlor. A controversy developed as three different stakeholders performed what they perceived to be objective, scientific assessments of the carcinogenic risk of Alachlor, only to arrive at three different answers. Given similar starting data and an objective approach, it was expected that the three parties would have agreed, yet they did not. Brunk *et al.*(6) argued that the controversy was not a result of bad science or incompetence, but instead was rooted in underlying value differences among the various parties. By explicitly applying concepts from systems theory, we illustrate how those differences were expressed as very different (but unstated) problem formulations. The point is clearly made that more explicit documentation and communication of the problem formulations would have revealed the underlying causes of the controversy and perhaps saved significant time and expense.

2.1. History of the Alachlor Controversy

In 1969, Monsanto Corporation received approval from the Canadian government to sell its herbicide Alachlor in Canada. Central to this approval were numerous toxicological tests performed by the private firm Industrial Bio-Test Laboratories (IBT) on behalf of Monsanto. In 1976, regulatory authorities in both the United States and Canada found these tests and many others conducted by IBT to be fraudulent, with the result that IBT was criminally charged and convicted.(16) This resulted in the unusual situation of a chemical being in widespread industrial use without any evidence of its safety. At the urgent request of the Health Protection Branch (HPB) of Health and Welfare Canada and under time pressures, Monsanto submitted a minimum set of replacement studies for review in 1982. A three-year study and debate ensued that ended with the HPB denouncing Alachlor as "one of the most potent carcinogenic pesticides presently in use"(6:11) and canceling its registration on February 5, 1985.

Monsanto legally appealed this ruling on March 4, and a Review Board was appointed to review the case on November 13, 1985. Rather than simply revisiting the material assembled by the HPB, the Board used its mandate to conduct its own independent risk assessment and investigation over a two-year period. This study was considerably broader in scope than those of the HPB and Monsanto, canvassing the opinions of a variety of groups, including Monsanto, several environmental groups, farmers' associations, and private individuals. The Board submitted its final report in November 1987, contradicting the decision of the HPB and recommending that Alachlor be reregistered for legal sale in Canada. However, the Minister of Health (who has the final approval in these matters) chose not to heed this recommendation, for reasons that were not clearly documented. To this day, Alachlor remains listed in the Canadian Environmental Protection Act as a prohibited substance.[17] Although differences between the Canadian and American cases are not explored in this article, it is interesting to note that the United States Environmental Protection Agency maintains its approval for Alachlor, which it refers to as the "second most widely used herbicide in the United States."[18] As of March 2002, Monsanto was still producing and selling in the United States the Alachlor-based herbicides Bullet, Lariat, Lasso, Micro-Tech, and Partner.[19]

There are four important observations to make concerning this history. First, this controversy is not a typical risk assessment situation. Not often is the safety of an approved and commercially important product suddenly called into question, nor do many risks undergo assessment by multiple bodies in sequence. Although not necessarily representative of what readers are likely to encounter, this case is valuable as a study of the effects of poor problem formulation. Second, the three major parties involved (the HPB, Monsanto, and the Review Board) did not work together or even simultaneously on their risk assessments. The HPB conducted its assessment first, based on data from and discussions with Monsanto. After the Review Board was appointed, Monsanto had the opportunity to present its own assessment, following which the Board also drew conclusions. Had representatives of the three parties met together to discuss some of the issues openly, it is entirely possible that the outcome would have been far less controversial. Third, the quantity of research available for these three assessments was quite limited because many of the original studies had been invalidated. Also, Monsanto was conducting further tests as the issues arose. The result of these factors was a great deal of uncertainty in the data, and a notable increase in the quantity of data seen by the Review Board over that reviewed by the HPB.

Lastly, Brunk *et al.*[6] reviewed the entire situation in hindsight, with the arguments of each party near at hand and in their entirety. This historical perspective gave them a considerable advantage in conducting their analyses and, as a result, they were able to identify a number of seeming contradictions in the original proceedings. The point for the reader is that such contradictions do not necessarily reflect on the ability of the original risk assessors—risk assessment is difficult at the best of times, and potentially horrendous in a regulatory setting.

2.2. The Main Issues

The following are the five main issues in the Alachlor risk assessment as extracted from Brunk *et al.*[6] It must be noted that Brunk *et al.* did not actually conduct a risk assessment themselves, nor did they intend to: they sought only to illustrate the differences between the risk assessments conducted previously. Similarly, the issues discussed here are not intended to be an exhaustive list (although they may be), nor even the correct ones. These are simply the aggregate, as seen in hindsight, of what each of the three main actors thought to be important. The purpose of identifying these issues is to show how together they form an overall picture of the situation and context of Alachlor, the "system" that must be interpreted in order to assess the risk.

1. The main issue was whether Alachlor was a carcinogen. From all the studies that were submitted for review, three were decisive. The first was a study that administered high doses of Alachlor to rats for an extended period. This study indicated a statistically significant incidence of cancer, and thus was strong evidence that Alachlor was a carcinogen. Another rat study administered a low dosage of Alachlor and produced cancer, but not enough for statistical significance. Lastly, a high-dosage study done with mice revealed a statistically significant difference between the control group and the test group for the female mice only. This study also had an unusually healthy control group. Thus, there was some doubt as to how this last study should be interpreted.
2. Alachlor was applied to crops using large-scale spraying devices, either automated or from moving farm vehicles. The applicators had to manipulate the storage containers, operate the sprayers, potentially refill vehicle tanks (depending on the equipment), and so forth. Therefore, another issue was that of applicator exposure to the chemical itself. The

exposure calculation had three key variables: whether the applicators were assumed to wear protective clothing (as the product warning labels stated they should), the percentage of Alachlor that would be absorbed into the body after contacting the skin, and whether the exposure should be amortized. This last variable deals with the fact that herbicide spraying occurs for perhaps six days out of the entire year: if a dosage rate of Alachlor per day is calculated, do we calculate the average for those days, or do we amortize that quantity over the entire year, or over the lifetime of the operator, or in some other fashion?

3. Alachlor's only significant competitor in the herbicide market was a similar product named Metolachlor, produced by Ciba-Geigy. Since banning or allowing Alachlor would affect the usage of Metolachlor, all three parties in the Alachlor debate compared the two products. The significant study for Metolachlor was a high-dosage rat study that produced statistically significant cancers. However, as the test protocol, test conditions, and type of rat were different from those used for the Alachlor study, a direct comparison between the toxicity of the two chemicals was difficult.
4. The discovery of Alachlor and Metolachlor in a number of farm wells in southwestern Ontario brought wider health and ecological issues into the debate. A complicating factor was the suspicion that many of those wells had been poorly constructed and thus were prone to contamination.
5. Lastly, there was an economic issue. Alachlor and Metolachlor were the only significant herbicides in use at the time, so removing one of them would give the other a virtual monopoly. Also, the economic benefits of chemical agriculture were significant enough that canceling both chemicals was never seriously considered.

These five issues have been graphically expressed in the system diagram shown in Fig. 1. The left-most column represents the most significant data in the controversy, some or all of which were used by the three parties in making their decisions. The two-piece boxes represent the major interim calculations or decisions, the top showing a description and the bottom a space for the value (to be filled in when we examine each party's specific case). The various flows indicate how those interim decisions combined for the final judgment on the risk of Alachlor. This diagram is a view of an information system, rather than a physical one, because in this case that is where our interest lies: we seek to understand how the various parties analyzed the information available to them to arrive at a conclusion. Again, this diagram does not pretend to be a complete view of the system at hand, nor is it necessarily sufficient for conducting a risk assessment; it simply represents the details of the system seen by Brunk *et al*. Note that Brunk *et al*. did not directly utilize any systems concepts in their work, nor did they express their findings in diagrammatic form. This and later systems diagrams concerning the Alachlor controversy are the work of the authors.

The main advantage of a diagram form is that the entire system is visible all at once. It becomes obvious which flows and effects are being considered (for example, it is clear that the overriding concern here is the final decision regarding Alachlor) and quick visual comparison between different views of the system becomes possible.

2.3. Views of the Three Parties

The belief of Brunk *et al*.[6] is that deep-seated, fundamental values of the risk assessor will influence those parts of the risk assessment process that are inherently normative. In this section, the overall mandate of each of the three parties is stated, and it is indicated how that mandate led to certain key values with regards to risk assessment.

The overall mandate of the HPB, as legislated by Canadian law, was to protect the health of Canadians. The government regulation of concern speaks of risk decisions being based on the "safety, merit, and value" of a product, but gives no guidelines for measuring or comparing these. Specifically, there was legislative ambiguity concerning whether the HPB should be making decisions based on a risk-benefit approach or a purely safety-based approach. As stated in its own risk assessment report, the HPB adopted the imperative of "reducing risk to a minimum." This led quite directly to a safety-focused risk assessment strategy that allowed a risk decision to be made on the basis of safety concerns alone, without consideration of potential benefits. It also led to the attitude known as the "precautionary principle": that in the event of uncertainty, a product is assumed to be dangerous until it is proven safe by meeting some established absolute standard. This effectively placed the burden of proof on Monsanto, and in this situation, with high

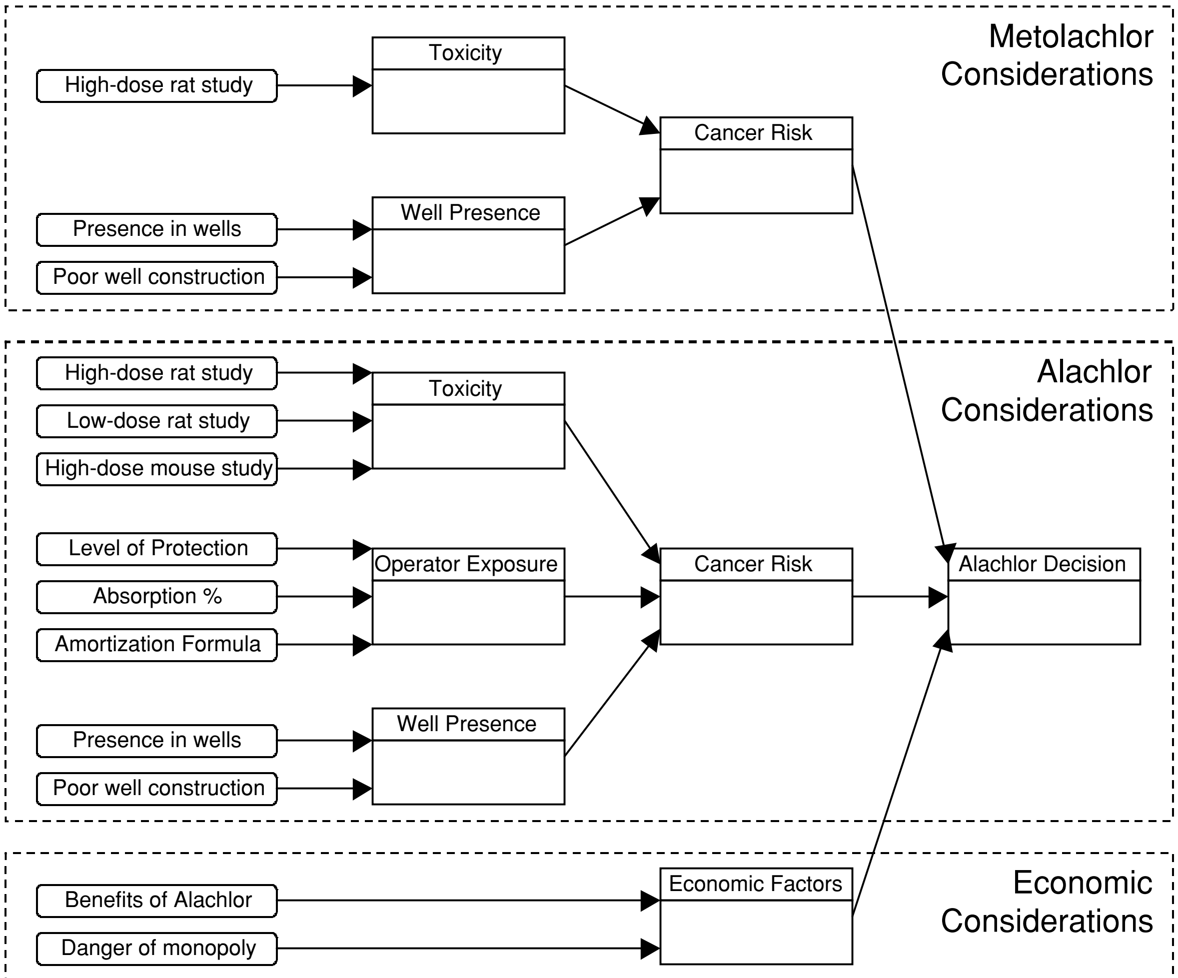

Fig. 1. The system as seen by Brunk *et al.*[6]

uncertainty due to the limited time available for Monsanto to provide data, the assignation of the burden of proof definitely affected the outcome. Certainly, in this controversy that assignation proved critical.

In contrast, the overall mandate of a corporate entity such as Monsanto is to market its products and make a profit. In the area of risk assessment, this generally translates into the key value of meeting the established minimum standard of acceptable risk. Note how different an approach this is than that held by the HPB: Monsanto aimed to meet a set level of risk, whereas the HPB sought to minimize the risk. A major result of this key value is that Monsanto believed that the decision of whether to cancel Alachlor could not be made on the basis of safety alone, but instead felt that benefits had to be considered as well. This belief caused Monsanto to adopt a risk-taking attitude, wherein one reaps the benefits of a situation unless the risk can be proven to be prohibitive. From this perspective, the burden of proof rested on the HPB. It should also be noted that Monsanto had enjoyed many years with Alachlor as a commercial success, presumably with no reported health incidents. In this context, the attitude that the HPB had to "prove" the product was dangerous before canceling Alachlor's registration is understandable.

The proceedings from the Review Board were the most detailed, so Brunk *et al.*'s analysis of the Board went slightly deeper. The mandate of the Board was stated quite clearly as "to be as objective and scientific as possible." The Board saw itself as the objective balance between the HPB's safety-first attitude and Monsanto's obvious corporate bias. One could label the Board somewhat of a peacemaker, in that the

HPB had overturned an existing ruling and caused an uproar that the Board needed to resolve. Further, the Board decided that it had the authority to initiate a third completely independent risk assessment, rather than simply reviewing the work to date. All told, the Board had a very different mandate from the HPB and the authority to ignore its work, a dangerous situation in that it made it possible for the HPB (the officially legislated body for health protection) to be bypassed. Brunk *et al*. attribute three key values to the Board: *rationalism*, the attitude that all decisions must be logical, objective, and based on sound data; *liberalism*, the belief that the government's role is to interfere only where absolutely necessary; and *pro-technology*, the general feeling that chemical and technological agriculture were positive. These values led to the Board dismissing any data or point of view that could not be strictly quantified, a stance that gave great weight to the precisely measured economic benefits. Their liberalism resulted in the burden of proof being assigned to the HPB, and their pro-technology stance led to a risk-taking attitude similar to that of Monsanto.

It must be understood that none of the parties involved explicitly acknowledged these values or appeared to realize that values were having an effect. The link drawn by Brunk *et al*. between these values and the viewpoints adopted by the three parties are quite clear in hindsight, yet were invisible to the parties at the time. While the studies done by each party were quite lengthy and involved a great deal of data, the final conclusions matched what could be predicted based solely on the discussion this far: the Board and Monsanto agreed that the HPB had insufficient cause to ban Alachlor. Therefore, the case is very strong that the differences between the values of the parties were not only factors in the controversy, but were decisive in the final outcome.

3. EXPLAINING THE CONTROVERSY

This study illustrates the effect that extra-scientific factors, such as the objectives, mandates, values, and perspectives of the risk analysts, can have on the results of a risk assessment. Although this was a matter of debate 20 years ago, the view that such effects are real and significant is now widely accepted in risk literature.[3,6,20] It could be argued that this effect applies only to highly complex risk situations, those that involve high-level methodological and philosophical issues. We take the view that the impact of extra-scientific factors is pervasive, but is only noticed or manifested when there are value-based disagreements. A group of engineers assessing the risk of equipment failure in a plant will likely have similar training and backgrounds and be working toward the same goal, and thus will have a common context from which to work. Although the choices they make and the overall approach taken may be influenced by this context, that effect will likely remain implicit and unnoticed as it will remain unquestioned. Everyone will likely agree on the process, so why question it? The introduction of an outside investigator with a different background may be necessary to reveal the underlying assumptions in such a circumstance. The key is that extra-scientific factors will always have an effect, regardless of whether they are questioned or made explicit, and regardless of how quantitative and clear-cut the problem at hand appears to be.

Brunk *et al*.[6] used an empirical approach to demonstrate how extra-scientific factors led to implicit assumptions and decisions that influenced the risk assessment process. What is required is a means to better identify and document these effects, so that the results of the risk assessment can be discussed and argued in the proper context (or, alternatively, so that the context itself can be argued without wasting time on the details). Such tools already exist in risk science in the form of systems modeling techniques. The explicit application of systems theory can help explain the mechanism by which extra-scientific factors have their effects, and can allow risk managers to more clearly document the assessment and management process. The preceding review of the Alachlor controversy identified the differences among three assessments of the same risk and showed how those differences were largely determined by the objectives and values of the risk assessors. We propose that those differences were more specifically differences in identifying the underlying system of interest. Thus, the impact of extra-scientific factors can be explicitly captured prior to initiating the risk assessment process via a system identification.

System identification is the process of identifying the structure of a system in terms such as components, interconnections, and environment. As previously mentioned, attempting to explicitly map out a complex system is usually quite frustrating but is often enlightening. Jordan[21] provides a detailed discussion of why a system identification is explicitly value- and observer-dependent, a discussion that parallels a number of authors' discussions of risk assessment.[6,9] A system identification performed by a varied group of stakeholders will quickly reveal differences of opinions and values, and thereby help clarify the key issues of contention. We believe that the difficulties at the heart of the Alachlor controversy and the difficulties typically encountered in a system identification exercise are one and the same. Thus, we can describe the classical risk assessment model in systems terms as follows.

1. *System Identification*: The process of specifying the system that will be considered in the risk assessment and the definition of the risk measure that will be extracted from that system. To a large extent, this is about deciding what information and interactions to include and what to exclude. This step is referred to in risk literature as "problem formulation" or "problem identification." Much of the work at this stage will be dictated by the facts and data surrounding the situation, but it is an inherently value-based exercise, the outcome of which will be greatly affected by who is participating. The final system description and proposed risk measure are an exact statement of what the risk assessors feel to be important, and will greatly influence the final evaluation of the risk.
2. *System/Risk Estimation*: As in the traditional view of risk assessment, this is the process of measuring and quantifying the parameters and values in the system. This is a predominantly scientific exercise, but can become subjective in the presence of uncertainty or "soft" issues. In practice, risk assessors must strike a balance between gathering only that data that comprises whatever risk measure will be used, and attempting to quantify in some fashion each and every part of the system being studied. The former approach is more efficient, but assumes that the risk measure is an appropriate one. The latter approach may uncover new information that results in the risk measure being changed or refined, at the cost of doing more work. Regardless of the balance struck, an explicit understanding of the system in question can help clarify the scope and limitations of the risk measure, increasing the transparency of the process to stakeholders.
3. *Risk Evaluation*: The process of translating the gathered and estimated data into a precise statement of the risk by evaluating the chosen risk measure.

The Alachlor controversy will now be reexamined in explicit systems terms. The sections below explain the key decisions made by each party during the system identification and estimation stages with respect to the various issues. These decisions formed the basis for each party's system of interest, implicitly determining what components were included and where the boundary was drawn. It becomes quite clear that each party was considering a sufficiently different system, such that different conclusions were highly likely, as in fact occurred. A clearer understanding at the time of what each party was doing would not necessarily have solved the fundamental disagreements, but it may have helped focus the arguments on the real issues.

The HPB interpreted both the mice and rat studies as being significant. Although the low-dosage rat study did not have statistical significance, the HPB felt that since the results were consistent with those of the high-dosage study, the low-dosage study was "biologically" significant. It felt that a reasonable exposure scenario involved no protective gear on herbicide applicators, 100% Alachlor absorption through the skin, and no amortization. The Metolachlor test results were interpreted very literally to mean that Metolachlor causes cancer in high doses only—one can contrast this with the very loose interpretation of the Alachlor low-dosage results. However, the HPB felt that any comparison at all between the two chemicals was irrelevant and that Alachlor should be judged by itself. The presence of Alachlor in wells was considered to be a highly significant fact as it implied that the risk of Alachlor was being imposed on the public. The economic issues were not addressed by the HPB at all. These interpretations amounted to a very different view of the overall system, as depicted in Fig. 2; those items that are greyed-out are elements that were not considered or addressed by the HPB.

Two facts are evident from the diagram. First, the HPB was quite selective in what information it considered to be part of the system and therefore the decision it had to make. Second, virtually every data point used (the left-most column) was one that boded poorly for Alachlor. The HPB had essentially only one difficult decision to make, namely, whether the mouse and rat data were indicative of Alachlor's effects on humans. As stated on the diagram in the box labeled "Toxicity," the HPB eventually decided that carcinogenic effects in two species of animals (mice and rats) constituted ample evidence of being a human carcinogen as well, resulting in the stance that Alachlor at any dosage level was a human toxin. The other two inputs

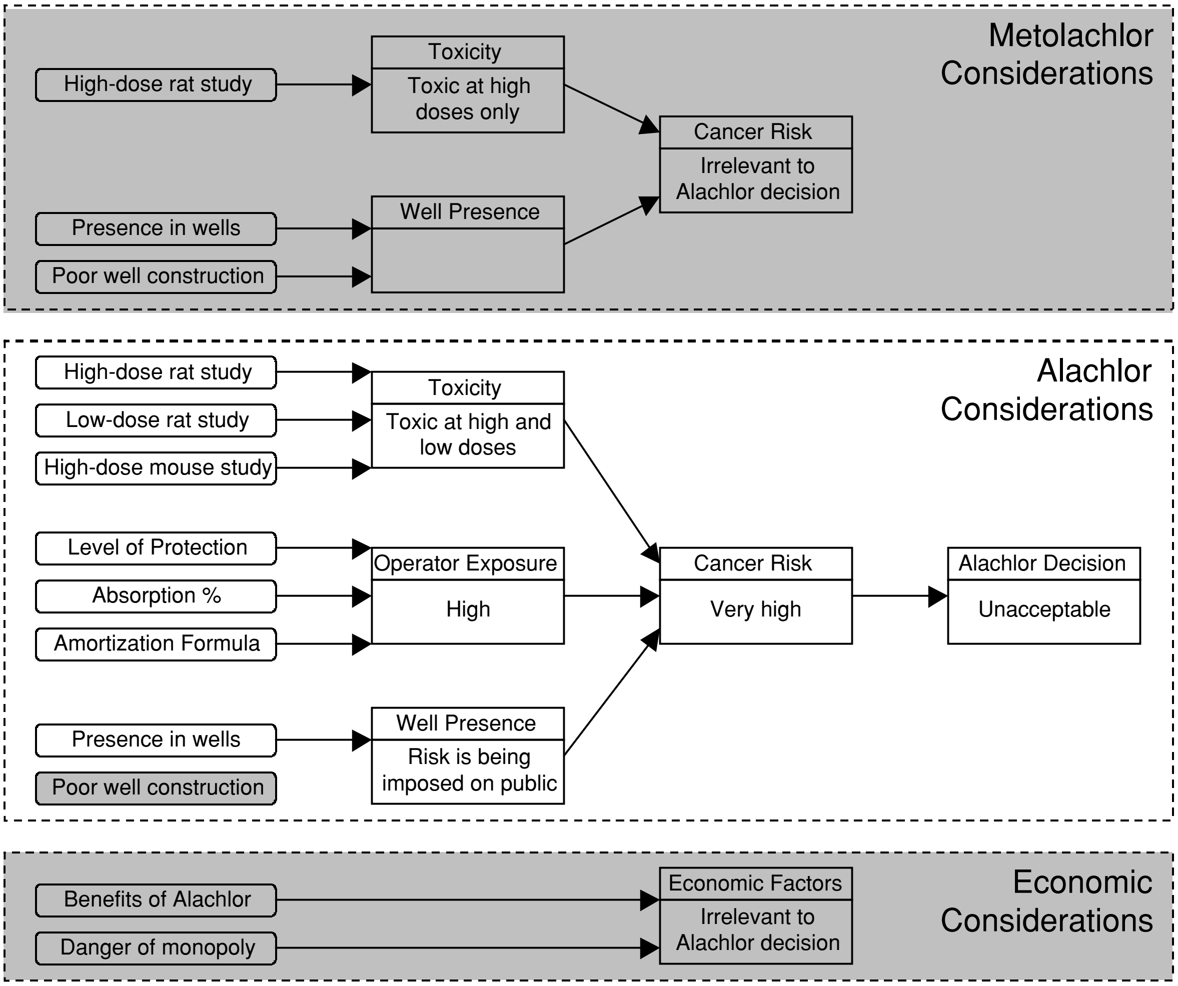

Fig. 2. The system as seen by the HPB.

to the HPB's evaluation of cancer risk were the applicator exposure level and the presence of Alachlor in wells, and the data used in both these evaluations cast Alachlor in a poor light. The obvious final conclusion was that Alachlor was unsafe.

Not surprisingly, Monsanto's view of the situation was very different. It felt the low-dosage rat study was inadmissible due to its lack of statistical significance and that the mouse study was aberrant and therefore invalid. Monsanto argued quite fairly that applicator behavior was beyond its control and that for this reason it should not be penalized for applicators not wearing protective gear. Earlier studies done on monkeys indicated that Alachlor absorption through a monkey's skin was about 10%; this figure was applied directly to the human situation. Amortization of the exposure was done over the lifetime of the applicator. The Metolachlor study was interpreted to mean only that Metolachlor was also a carcinogen, and that due to the differences in the studies, the two chemicals could not be ranked in terms of their toxicity. Again we see a contrast in interpretation between this loose interpretation and the rigidly scientific view of the low-dosage rat study.

Monsanto claimed that the presence of Alachlor in wells was due to poor construction of those wells. This made a difference because it allowed Monsanto to argue that the well owners, in choosing to live with a shoddy well, were voluntarily accepting the risks that went along with it, including the risk of Alachlor. Finally, Monsanto made frequent comparisons to Metolachlor (its presence in wells, the potential for a monopoly, etc.), and supplied detailed data on the positive economic impact the use of Alachlor

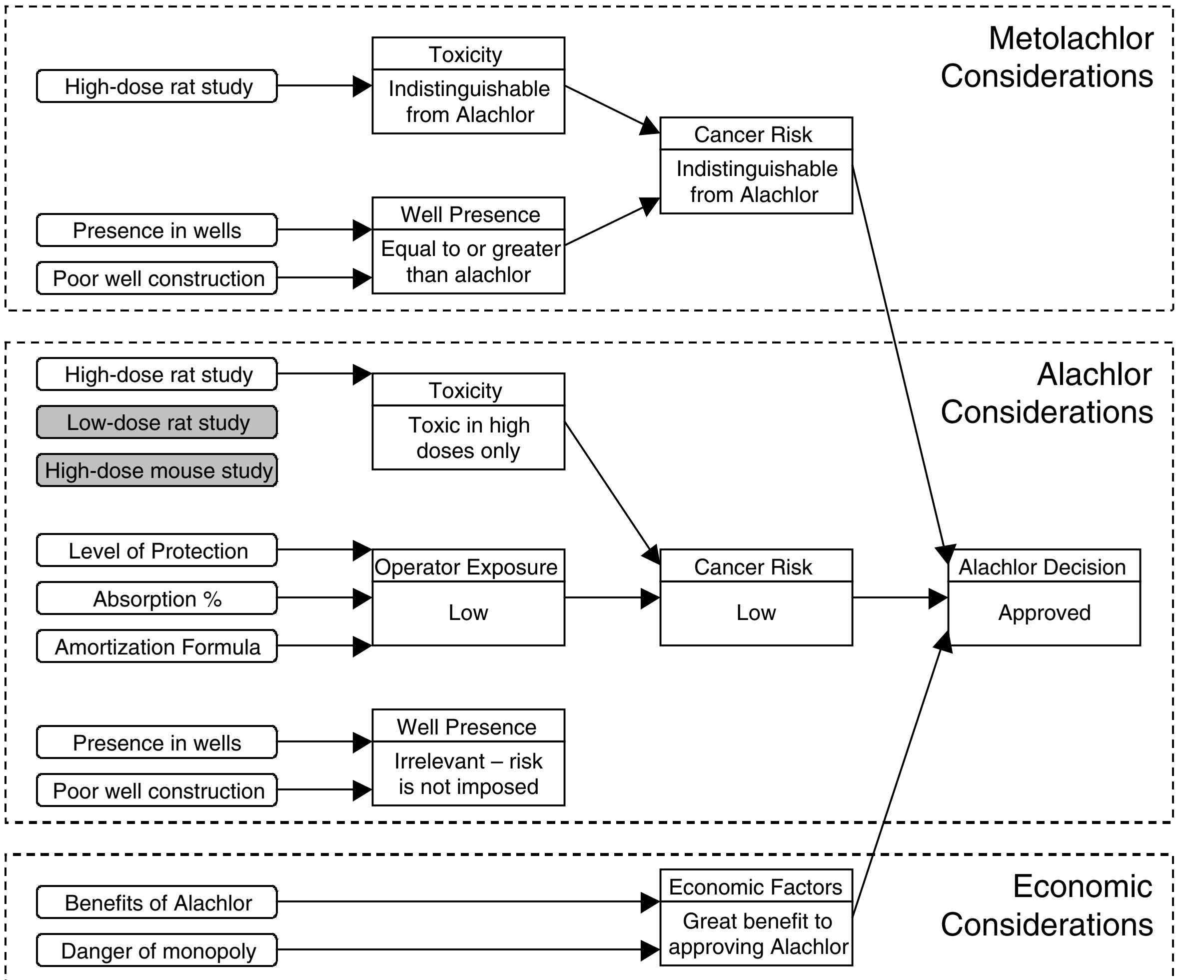

Fig. 3. The system as seen by Monsanto.

was having. All this contributed to a view of the system, portrayed in Fig. 3, that was very different from that of the HPB shown in Fig. 2.

Here we see not only different interpretations of the data, but also a vastly different view of the system. The most significant differences are that both positive and negative data points are now being considered, and that a comparison is being made to a competing product. Without going further, both these points suggest that the final decision will be more difficult. Monsanto's exposure calculations gave a result well below the dosage found to cause cancer in rats, and the company questioned the validity of extrapolating the rat results to humans. In the end, Monsanto concluded that the risks of Alachlor (if any) were more than compensated for by the benefits or effectively nullified by being indistinguishable from Metolachlor.

The Review Board was the last of the three parties to perform its assessment, and in many ways it took the middle ground between the HPB and Monsanto. The Board agreed with Monsanto with regard to the Alachlor studies in concluding that only the high-dosage rat study was significant. It also assumed that applicators would wear the recommended protection, but estimated absorption and amortization rates to be in between those of the HPB and Monsanto. Metolachlor and Alachlor were equated throughout in terms of carcinogenic effects, their presence in wells (which was felt to be small enough as to be within reasonable limits), and in their economic benefits and potential for monopoly. This comparison was of great import because of the three options considered by the Review Board: cancel Alachlor and keep Metolachlor, keep Alachlor and cancel Metolachlor, or

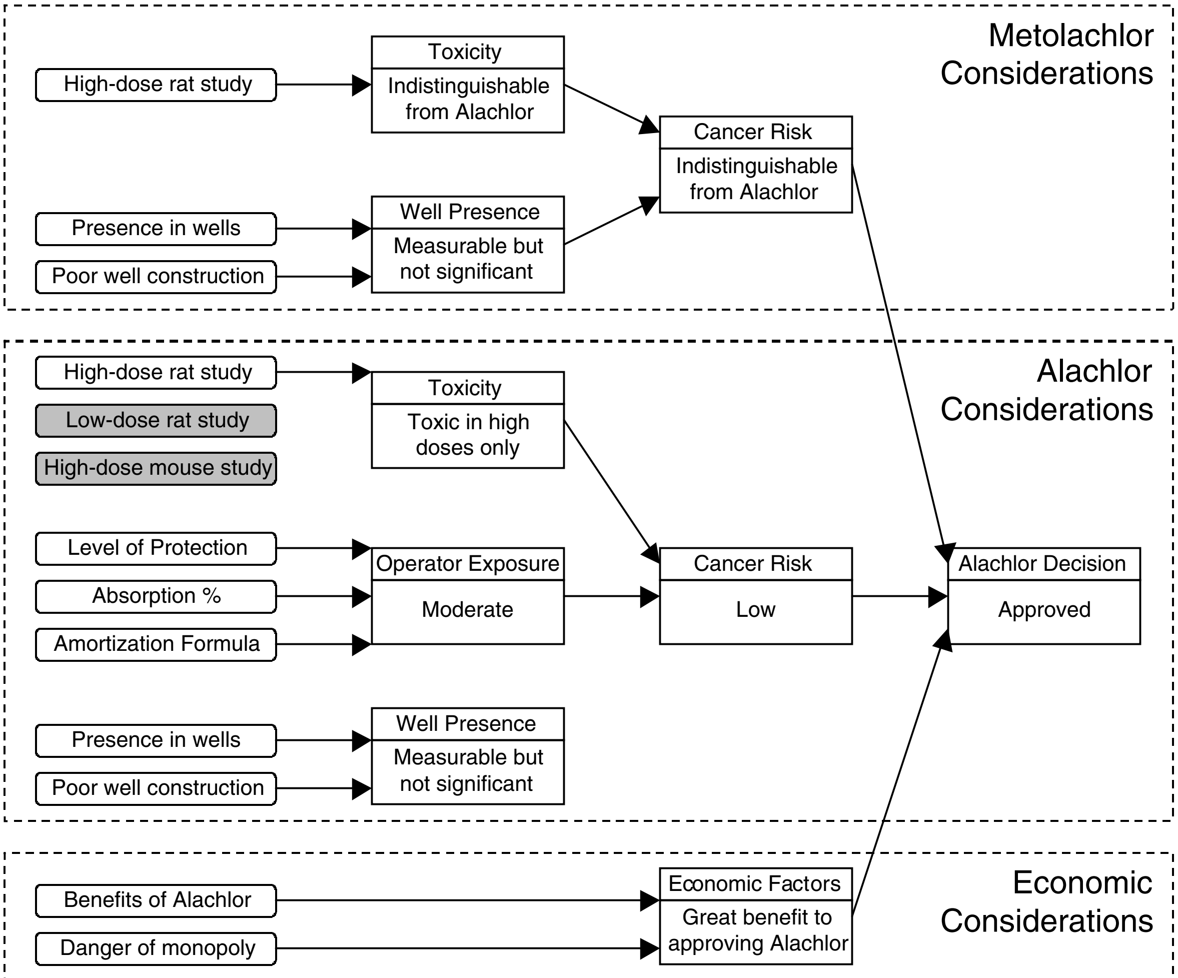

Fig. 4. The system as seen by the Review Board.

keep both. Canceling both was never seriously considered due to the ramifications on farming efficiency and income, and since the two were considered equal, there was no reason for canceling one and keeping the other. The Review Board's view of the system can therefore be drawn as shown in Fig. 4.

For the Review Board, the final decision was largely a question of comparing Alachlor to Metolachlor. Since no appreciable difference could be found, and as the Board's exposure calculations estimated applicator exposure to Alachlor to be three to four orders of magnitude below that known to cause cancer in rats, the Board concluded that there was a "reasonable margin of safety" for Alachlor. It is clear from the diagram that the Board basically concurred with Monsanto in its view of the overall situation, even though there were some numerical differences. There are two notes that can be made regarding this conclusion. First, the lack of an appreciable difference between the two chemicals is not at all surprising considering how little information was available on Alachlor, but the Board did not specifically acknowledge this uncertainty effect. Second, the Board defined a "reasonable margin of safety" as being three to four orders of magnitude, without stating any justification for that number. What was reasonable to them might not be to others who follow them and read their analysis, so again the argument for more explicit clarifications and documentation applies.

Examination of the three system diagrams clearly shows the roots of much of the controversy. Each party brought to their risk assessment a unique perspective, which was manifested as a different definition of the system during the problem formulation. Judging by the final results, general agreement on the system definition seems to have led to agreement on the final decision, suggesting that the system view itself may have been the deciding factor. None of the parties seemed to be aware of either the effect of their perspective or the differences in their views of the system. As a result, the debate focused on the science and estimation, on the steps that happened after the system identification; the view of the system being worked from was never discussed. But since the system identification itself largely settled the issue, all arguments were moot: no party's arguments made sense to any other party since they all had a different view of the system. (An obvious question is, therefore, "What is the correct view of the system?" but to put forward an answer would be missing the point. The view of the system in Fig. 1, the view of Brunk *et al.*, is a more encompassing view than any of those held during the controversy, but this does not mean that it is more or less accurate or "better" or that it can produce a better risk decision.) An obvious conclusion is that the system identification stage was happening implicitly, with no party aware of what was happening or taking the time to document the assumptions they were making.

The role of severe uncertainty is also well illustrated in this study. If there are insufficient data to prove something either dangerous or safe, then the answer obtained will depend on the question that guides the analysis. The question "Can you prove that Alachlor is safe?" will receive a "no" for an answer, leading to the conclusion that Alachlor is dangerous. But asking "Can you prove that Alachlor is dangerous?" will also yield a negative, from which we would conclude that Alachlor is safe. Again, note the importance of assigning the burden of proof. When uncertainty is this high, it is most prudent to simply answer "we don't know" and to obtain further information to clarify the uncertainties. Unfortunately, the unusual circumstances of the Alachlor case pressured the Review Board to deliver a timely decision and effectively proscribed the "don't know" answer.

4. DISCUSSION

The authors believe that the issues behind the Alachlor controversy are not unique to that one case, but are pervasive in complex risk situations. In particular, there are two lessons that can be learned: the value of explicitly applying systems theory during the problem formulation stage, and the importance of separating the problem formulation from the risk estimation itself.

Regardless of whether it is acknowledged, the process of system identification followed by risk estimation is what is truly occurring in risk assessments. Accepting that a system identification underlies risk problem formulation and using the tools of systems theory to complete it provides a mechanism by which many of the value and perspective issues can be analyzed and captured. Indeed, these perspective issues are classic systems issues, discussed at length in the systems theory literature.[13,15,21,22] They manifest themselves as disagreements about what is important enough to be considered (boundary issues), what the overall mandate of the risk investigation is (purpose of the system model), and what the cause-and-effect relationships really are (interconnections). The vocabulary and tools of systems theory provide a common language for risk researchers to use in dealing with these issues. We believe that making the transition to performing formal system identifications prior to initiating the estimation process will provide better overall results to the decisionmakers and thereby lead to better decisions. In some cases, this transition will require simply the explicit statement that it is in fact a system study that is being undertaken; in other situations, the introduction of the more complete systems approach will result in significant disagreements being raised at an early stage.

It is important to note that an explicit systems approach will work effectively for both simple and complex cases without adding undue overhead. If a system identification is undertaken prior to a risk assessment and significant disagreements develop, it likely indicates that the situation under review is more complex than initially anticipated. In such situations, it is best to deal with the fundamental issues and disagreements as early in the process as possible, rather than after the results are published (as is often the case). If the situation being examined is actually quite straightforward, then the process of systems identification will proceed smoothly and quickly and will produce a useful, detailed model of the system. It will also make explicit for those who follow or review the work exactly what was considered and what was ignored, it will force the examination and recording of assumptions, and it will provide a tool for communicating findings and conclusions. In situations of high uncertainty, a risk assessment approach based on a purely numeric calculation may find that there is insufficient data for a reliable analysis, leaving the investigators with nothing but a half-complete calculation and an enhanced personal understanding of the situation. By utilizing the systems approach from the start, the investigators will at worst develop the best available model of the system in a usable and presentable form, and, ideally, will ascertain the quantities for multiple types of risk calculations.

There is considerable support for adopting the systems approach in risk assessment. Haimes[2] nicely positions the process of risk assessment within a systems analysis framework and stresses the importance of doing so. The Canadian Standards Association guidelines[9] and Fayerweather *et al*.[23] implicitly encourage a systems approach throughout the risk management process. Kalbfleisch *et al*.[24] take the stance that risk assessment should encourage enhanced understanding of the situation being studied; if that understanding is best captured and communicated by the calculation of probabilities and formulae (as can be the case in specialized technical situations), then that technique should be used. Otherwise, Kalbfleish *et al*. feel that the analysis should not be limited to the calculation of a single number, as a one-number summary may serve more to obscure the system than to present a clear picture, but instead should focus on developing a useful overall model. Similarly, the Royal Society report on risk states that "the main benefit of estimating risk lies in the achievement of detailed understanding of the engineered system."[3:29] Lastly, the systems approach necessitates at least the consideration of underlying values and assumptions, which both McDonald[25] and Funtowicz and Ravetz[26] insist is necessary in this era of decision making.

The examination of the Alachlor case has also underlined the importance of completing a clear system identification as part of the problem formulation before initiating the risk estimation work. We can view system identification as the transition between the risk management or decision-making mindset required during problem formulation and the detail-focused, quantitative mindset that must be present in risk estimation. The overall management context will determine factors such as the current mandate and objectives, the key values that are influencing decisions, and the areas of concern to stakeholders. If from that context a question emerges that a risk assessment can help answer, then a system identification must be performed as part of giving the risk analysts and technical specialists proper direction. In a sense, the system identification plays the role for a risk analyst that a statement of work plays for a contractor or a requirements specification plays for an engineer: it defines the objectives, scope, constraints, and key measures that must be used. Only when the risk managers can clearly articulate the system of interest and the final form of the risk measure should more quantitative work proceed, because only under those conditions is it likely that the answer received will be both applicable and useful.[5] Fayerweather *et al.*[23] discuss a similar process wherein a group of selected experts collectively builds an influence diagram (essentially a form of systems description) to describe the situation at hand, then hands that diagram to the analysts to quantify and thereby generate a risk measure.

Other authors have discussed the involvement of oversight committees[27] and, on a much broader scale, public interest and opinion. Environmental and health risk issues are examples where a layperson may have as valid a perspective as an expert. The system identification phase is an ideal venue for such involvement because it is the step that most directly affects what has to be measured in the risk assessment and because decisions made at this stage will impact the quality of all the work to follow. Also, the systems approach permits a broad range of opinion or influence to be incorporated into the decision process. By canvassing those diverse views and incorporating them into the system model, a broad spectrum of knowledge can be brought to bear on the decision. The opposite case involves calling in "risk experts" to deal with any and all situations involving risk, which can result in important information being overlooked. Brunk *et al*.[6] comment several times on the importance of expert opinion not overshadowing or invalidating lay knowledge. Deciding on who should be part of the decision process is often a battle in itself,[13] but the systems approach does ensure that the question is asked.

Regardless of how clear a mandate is given to the risk analysts, the risk assessment process itself will often raise new questions that require normative decisions or assumptions to be resolved. This can happen for a number of reasons, including the lack of a proper or sufficiently detailed system identification, a lack of understanding or information about the true nature of the situation, or a high level of uncertainty. This is a natural part and a great benefit of risk assessment, for each new issue encountered indicates that something new has been learned and overall understanding of the situation enhanced. Where the risk assessment process becomes controversial is when the analysts make the necessary decisions or assumptions themselves without acknowledging or documenting what is happening, as happened in the Alachlor controversy. Such actions open the analysts' work to criticism from those who disagree with the assumptions made or who would have done things differently. The proper role of the risk analysts is to return to the oversight committee to vet those decisions and assumptions or, at the very least, to document them for future reference. Put another way, those answering the question should clarify the question where necessary rather than guessing at what the question means. This form of dialogue can become iterative and quite lengthy in a complex situation, but does not preclude positive action from being taken. As noted by McDaniels *et al.*,[27] it is best not to spend time looking for the "right" answer only to argue about it afterwards, but instead to take a positive step forward then evaluate the progress made. Another way to state this approach is that risk assessors should discuss context, objectives, system extents, and assumptions at least as often as they discuss actual results.

5. FURTHER EXTRAPOLATIONS

In addition to the suggestions discussed above, examining risk assessment from the perspective of classical systems theory also prompts several ideas concerning fundamental risk concepts. Here we suggest how the systems perspective can provide insight into the definition of risk itself, and how risk can be viewed in an overall decision-making context.

This article has suggested that extra-scientific factors have their impact primarily during system identification, before any examination of specific quantities is initiated. This leads directly to the conclusion that while risk is indeed not a property of a single entity, it does appear to be a property of a system. Just as connectedness and complexity are concepts applicable to systems but not to single entities, so risk appears to have meaning only in the context of a system. This stance dovetails with the view of numerous authors[1,6,20] who have in various ways put forth the idea of risk as not being an inherent property of a thing. An implication is that changing the system could very easily change the estimate of the risk, which is in fact what we observed in the Alachlor example.

Further, because the assessment of risk is based on an underlying system (whether implicit or explicit), and since a view of a system is an inherently subjective entity, systems theory supports the modern view that risk itself is an observer-dependent phenomenon. Whereas the traditional quantitative approach inferred that risk was an intrinsic property that could be accurately measured, the ideas here support the view that risk is a relational property between the situation and the observer. Thus, the assessed severity of the risk could easily be altered by changing the system model, the perceiver, or the rules for risk evaluation. Risk managers and decisionmakers should expect differing perceptions and attitudes toward risk situations and should understand that such differences are legitimate and not due to misconception or ignorance. Such differences reflect a diversity of values and perceptions that should be leveraged and managed for the benefits they can bring rather than eliminated for the sake of easy agreement. Our science, methodologies, and techniques are tools that can be used to measure, but they cannot compare apples to oranges and cannot magically account for differences in personal values. They are tools to be used after the various perspectives have been recognized and accepted, and in a mutually agreed-upon search for good decisions.

Because a risk assessment typically occurs within some management or decision-making context, the final evaluation of the risk can be viewed as one criterion for a decision. Goldstein[28] compares risk assessment to the various indicators used in economics in order to illustrate the point that regardless of what else it may be, risk is but one factor in decision making. Traditional risk management assumes that risk is the primary concern in the decision process, and therefore does not always account for other factors. The typical risk assessment process therefore serves to measure a narrow, one-dimensional view of risk. In practice, most decisions involve a number of criteria, of which risk may or may not be the most important. Haimes[2] explains the holistic aspects of risk assessment and management as a hierarchical, multiobjective framework within which there may be conflicting and noncommensurate objectives. Besides its multiple objective nature, a given risk problem almost always involves multiple interest groups that are in conflict over the interpretation of the problem and what can be done to resolve it. Chapter 27 of Sage and Rouse[8] provides a detailed discussion and list of references on multiple objective decision making and conflict resolution.

In contrast to the traditional approach, the systems-oriented approach focuses on developing and quantifying (to the degree necessary or possible) a model of the system, which can then be used for evaluating a number of criteria. The same system model that allows an evaluation of the overall risk can also provide information on benefits, environmental impacts, resources required, or whatever other criteria

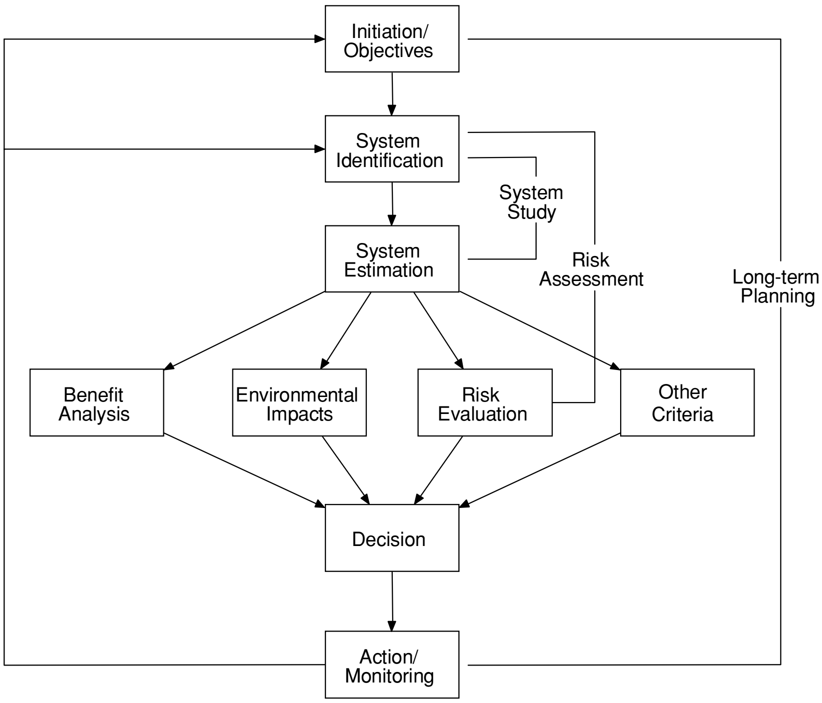

Fig. 5. A view of risk in long-term planning.

are necessary. Most importantly, an integrated system model can assist the decisionmaker in putting the various criteria into perspective. Traditional risk assessment assumes that risk has already been decided upon as the chief decision criterion; the systems approach allows the prioritizing of criteria to be delayed until the system is well understood. The caveat is to ensure that the effort being spent on the decision process is justified by the scope, importance, or stakes of the decision. No one would recommend full systems models constructed for deciding trivial issues; in fact, most decisionmakers use simplistic rules that work most of the time.[29] The true skill lies in applying resources to problems and decisions in as efficient and effective a manner as possible.

These ideas can help clarify how risk assessment fits into the broader context of risk management and decision making. Rather than the process focusing exclusively on risk to the exclusion of other considerations, we now envision a more integrated approach that incorporates risk into an iterative management procedure that accounts for many criteria other than risk, as shown in Fig. 5.

6. CLOSING

This article has examined risk and risk assessment from a systems perspective in an attempt to clarify old ambiguities and to expand the field. We began by discussing how underlying values and perspectives always have an effect on risk assessment. We then utilized concepts from systems theory to propose that risk assessment actually begins with a system identification step, conducted by the risk managers and decisionmakers. Risk was loosely characterized to be an observer-dependent property of a system whose primary value is as a criterion for decision making. The usefulness of a system model for both simple and complex risk situations and for supplying information to decision criteria other than risk was discussed. Finally, we noted the impact of the holistic systems perspective on decision making and long-term planning. In the overall context of decision making under uncertainty, we have investigated how risk and systems theory affect the decision-making process.

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