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# 1 The Basics

## 1.1 WHAT IS RISK?

Risk is a measure of the probability and consequence of uncertain future events. It is the chance of an undesirable outcome. That outcome could be a loss due to fire, flood, illness, death, financial setback, or any sort of hazard, or a potential gain that is not realized because a new product did not catch on as hoped, your investment did not produce expected benefits, the ecosystem was not restored, or any sort of opportunity is missed. What usually creates the “chance” is a lack of information about events that have not yet occurred. We lack information because there are facts we do not know, the future is fundamentally uncertain, and because the universe is inherently variable. Let’s call all of this “uncertainty” for the moment.

Given the presence of a hazard or an opportunity, there are two important components to a risk: an undesirable outcome or consequence and the chance or probability it will occur. Risk is often described by the simple equation:

$$\text{Risk} = \text{Consequence} \times \text{Probability} \quad (1.1)$$

Consider this expression a mental model that helps us think about risk rather than an equation that defines it. What this expression is conveying is not so much that this is the manner in which all risks are calculated (they are not) as much as that both of these elements must be present for there to be a real risk. If an event of any consequence has no probability of occurrence, there is no risk. Likewise, if there is no consequence or undesirable outcome, then there is no risk.

A hazard is the thing that causes the potential for an adverse consequence. An opportunity causes the potential for a positive consequence. If a population, an individual, or some asset of interest to us is not exposed to the hazard or opportunity, then there will be no consequence and no risk. The range of possible consequences, loss of life, property damage, financial loss or gain, improved environmental conditions, product success, and the like is vast, but even similar types of consequences can vary in frequency, magnitude, severity, and duration.

It is not likely that many risk professionals would agree with such simple definitions. There are any number of alternative definitions in use or found in the literature. Some purists prefer to define risk entirely in terms of adverse consequences, ignoring the chance of gains that may not be realized. These risks of loss are sometimes called pure risks. Some definitions specify the nature of the consequences. The U.S. Environmental Protection Agency (EPA), for example, “considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor” (EPA 2010).



Storms, hurricanes, floods, forest fires, and earthquakes are examples of natural hazards. When humans and human activity are exposed to these hazards there are risks with consequences that include loss of life, property damage, economic loss, and so on. There are human-made hazards by the scores: tools, weapons, vehicles, chemicals, technology, and activities. They can pose risks to life, property, environment, economies, and the like. Health hazards comprise their own category and include pathogens, disease, and all manner of personal health difficulties and accidents that can arise. These risks of adverse consequences are traditional examples of risk.

Less widely accepted as risks, among the risk analysis community's members, are potential gains or rewards. Would anyone say they risk a promotion or an inheritance? Probably not, as this is not the traditional use of the word. Nonetheless, when there is some uncertainty that the gain will be realized, it qualifies as a risk under the definition used here. The International Organization for Standardization (ISO 2018) defines risk as the effect of uncertainty on an organization's objectives. This is clearly broad enough to include uncertain opportunities for gain. Risks of uncertain gain are often called speculative risks.

### THE LANGUAGE IS MESSY

The language of risk is relatively young and still evolving. The seeds of risk analysis are sown across many disciplines, and each has found it useful to define the terms of risk analysis in a way that best serves the needs of the parent discipline. The EPA, for example, identifies 19 variations on the meaning of risk in their *Thesaurus of Terms Used in Microbial Risk Assessment*, which eponymously takes a narrow focus on the concept of risk (EPA, 2007).

Frank Knight (1921) is credited with the first modern definition of risk. Kaplan and Garrick (1981) attempted to unify the language with their famous triplet. There is not yet any one universally satisfactory definition of risk nor of many of the other terms used in this book (ISO, 2018). ISO 31000, for example, offers quite a different lexicon than the one used in this book. There is more agreement on the practice of risk analysis than there is on its language.

For those who prefer to think of risks only as adverse consequences, it takes only a small convolution of thought to say that not realizing the gain/promotion/inheritance is the adverse consequence. In any event, loss and uncertain potential gains are considered risks throughout this book. Know that some would prefer to distinguish and separate risks and rewards more carefully.

Thus, we have pure risks, which are losses with no potential gains and no beneficial result, and speculative or opportunity risks, which are generally defined as risks that result in an uncertain degree of gain. They are further distinguished by the fact that pure risk events are beyond the decision maker's control, the results of uncontrollable circumstances, while speculative risks are the result of conscious choices made in decision making. These two types of risks lead to two distinct risk management strategies: risk avoiding and risk taking. Risk managers select options that will enable them to reduce unacceptable levels of pure risk to acceptable or tolerable levels. Risk



managers also choose to take risks when they select an alternative course of action to pursue potential gains. So, risk managers function as risk avoiders when they decide how best to reduce the adverse consequences of risk and as risk takers when they decide how best to realize potential gains in the future. Uncertainty makes all of this necessary; there is no risk without uncertainty.

### **A FEW PROPOSITIONS ABOUT RISK**

- Risk is everywhere
- Some risks are more serious than others
- Zero risk is not an option
- Risk is unavoidable

Therefore, we need risk analysis to:

- Describe these risks (risk assessment)
- Talk about them (risk communication)

There is very little we do that is risk free, although risks certainly vary in the magnitudes of their consequences and the frequencies of their occurrences. A leaky ballpoint pen is not in the same class of risks as an asteroid five miles in diameter colliding with Earth.

Risk is sometimes confused with safety. In the past, we have tried to provide safety, and getting to safety has been the goal of many public policies. The problem with a notion like safety is that someone must decide what level of chance or what magnitude of consequence is going to be considered safe. That is a fundamentally subjective decision, and subjective decisions rarely satisfy everyone. Risk, by contrast, can be measurable, objective, and based on fixed criteria.

Safety has been defined in a number of legislative and administrative frameworks\* as a “reasonable certainty of no harm,” a phrase extended in some contexts to include “when used as intended.” The very language chosen suggests the uncertain existence of a residual risk, and if there is a residual risk, then safety in any absolute sense is a psychological fiction. In fact, the act of calling something safe is a risk management decision.

An alternative to looking for safety and providing margins of safety is to look objectively for risk. That means we have to be able to objectively describe these risks for ourselves and others. Then, we need to be able to communicate that information to one another. Finally, we need a means of determining when a risk is not acceptable and needs to be avoided or managed to some level we can tolerate. This is basically the risk analysis process.

Because uncertainty gives rise to risk, the essential purpose of risk analysis is to help us make better decisions under conditions of uncertainty. This is done by separating what we know about a decision problem from what we do not know about it. We use what we know and intentionally address those things we do not know

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\* The Food Quality Protection Act of 1996 is one such example.



in a systematic and transparent decision-making process that includes effective assessment, communication, and management of risks.

Many people in many different disciplines figured this all out a while ago. They also articulated these ideas in the language of their own disciplines, and that has given birth to a wonderfully chaotic language of risk. Many of these discipline-based uses of risk analysis have deep enough roots that practitioners are sometimes reluctant to consider other views of this new composite discipline. There may be emerging consensus about some ideas, but there is little or no universal agreement about the language of risk analysis. That makes it difficult for anyone trying to understand the essence of risk analysis to get a clear view of just what this is all about.

Risk analysis is a framework for decision making under uncertainty. It was born spontaneously, if not always simultaneously, in many disciplines. It has evolved by fits and starts rather than by master design. Its practice is a wonderful mess of competing and even, at times, contradictory models. Its language borders on a babel of biblical proportions. And still it has begun to become something we can all recognize.

Many practitioners do not even recognize the term “risk analysis.” They would call this framework for decision making under uncertainty “risk management.” They could argue, effectively, that it includes risk assessment and risk communication. The language of risk is quite messy and not likely to be reconciled any time soon.

This book makes no pretense toward unifying, standardizing, or exemplifying the language, definitions, or models of the science of risk analysis. What it does modestly attempt is to distill the common elements and principles of the many risk tribes and dialects into serviceable definitions and narratives. There is more that unites risk analysis and risk management than divides it. Once grounded in the basic principles of risk analysis, or, if you prefer, risk management, the reader should feel free to venture forth into the applications and concepts of the many communities of practice to use their models and speak their language. Now, with this simple understanding of risk and this caveat in mind, let’s consider a few more important questions.

## **1.2 HOW DO WE IDENTIFY A RISK?**

It is precisely because the language is so messy that it is important to be able to identify a risk clearly. There are five essential steps to a good risk identification process:

- Identify the trigger event.
- Identify the hazard or opportunity for uncertain gain.
- Identify the specific harm or harms that could result from the hazard or opportunity for uncertain gain.
- Specify the sequence of events that is necessary for the hazard or opportunity for uncertain gain to result in the identified harm(s).
- Identify the most significant uncertainties in the preceding steps.

### **1.2.1 TRIGGER**

Something initiates the need for risk identification. It could be a discrete event like a study authorization or a flood, information obtained from stakeholders, the



accumulation of scientific knowledge, an intentional search for risks, and the like. It helps to note the event that triggers a specific risk coming to light.

### 1.2.2 HAZARD OR OPPORTUNITY

A hazard is anything that is a potential source of harm to a valued asset. Hazards include all natural and anthropogenic events capable of causing adverse effects on people, property, economy, culture, social structure, or environment. Hazards can be readily fit into categories of hazards like biological, chemical, physical, and radiological agents. Examples of hazardous events include terrorism, infrastructure failure, crimes, fires, hurricanes, wars, explosions, seismic events, hydraulic fracturing, automobile accidents, and so on.

An opportunity is any situation that causes, creates, or presents the potential for an uncertain positive consequence. It is any set of circumstances that presents a good opportunity for progress, advancement, or other desirable gain to a valued asset. The gain may be personal, organizational, communal, societal, national, or global. Opportunities include potential financial gain through new products, ventures, and behaviors, they also include such things as cost savings, ecosystem improvements, reduced traffic congestion, and so on.

#### LOSS RISK

*Trigger:* Congressional authorization

*Hazard:* Aquatic nuisance species (ANS)

*Harm:* Reduced landings of commercial fisheries

*Sequence:* Pathway exists → ANS arrives at pathway → ANS survives passage thru pathway → ANS colonizes in commercial fishery waterway → ANS spreads and outcompetes commercial fishery

*Uncertainty:* Arrival time, survival through pathway; will it outcompete

#### SPECULATIVE RISK

*Trigger:* Competition among ports

*Opportunity:* Reduce transportation costs

*Harm:* Reductions not realized

*Sequence:* Harbor improvements → fleet composition does not change → tonnage lost to other ports

*Uncertainty:* Fleet composition, trade patterns, technology changes

### 1.2.3 CONSEQUENCE

Determining the specific harm in a risk situation must precede an assessment of the probability of that harm. Thus, consequence comes before probability in the risk identification task. If one begins with the probability, it is easy to become confused: the probability of what? Once the consequence is identified, it is easier to identify its probability. Analysts must identify the specific harm or harms that can result from



a hazard. Likewise, they must identify the disappointing and unwelcome results that can occur with an opportunity for uncertain gain.

There may be more than one undesirable outcome. If so, identify all the relevant harms to be assessed. Floods for example can result in loss of life, property damage, business loss, and other kinds of harm. Ecosystem restoration could increase habitat, improve water quality, increase ecosystem services, and offer other potential gains.

#### **1.2.4 SEQUENCE OF EVENTS**

For each harm identified, the analyst should identify the specific sequence of events that is necessary for the hazard to result in the identified harm or consequence. The likelihood of that precise sequence of events occurring will define the probability of the risk. When there is more than one pathway from the hazard to the harm, each relevant pathway ought to be identified. In a similar fashion, the sequence of events from an opportunity to an undesirable outcome ought to be identified.

#### **1.2.5 UNCERTAINTY**

The initial identification of a risk is likely to be uncertain. Some consequences, that is, harms, may be uncertain and the sequence of events that leads to them may, likewise, be uncertain. Even when the consequences and their causative events are known, there can be uncertainty about their magnitude, frequency, duration, and the like. It is the analyst's job to identify the most significant uncertainties that attend a risk so that they can be addressed in assessment and management.

This identification process provides clarity about the risk of concern. It is common practice to speak about the risk of acrylamide, the risk of dam failure, the risk of bankruptcy, and so on. This shorthand communication often leads to considerable confusion about the true nature of a risk. For risk managers, assessors, and communicators, it is essential that they are able to clearly and unambiguously identify risks of concern with a process like that above before they revert to shorthand descriptions of risks.

### **1.3 WHAT IS RISK ANALYSIS?**

Risk analysis is an emerging science, and it is a decision-making paradigm. Terje Aven (2018) makes a powerful argument for risk analysis as a new emerging science. Although it is rapidly developing it is not yet widely regarded as a science unto itself. As a paradigm, it is capable of producing knowledge about risks and risky activities in the real world. As a science, it also produces knowledge about concepts, theories, frameworks, methods, and the like to understand, assess, communicate, and manage risks. This latter knowledge set makes risk analysis as much a science as statistics is, for example. The risk analysis paradigm presented in this text is frequently referred to as risk management, especially by those who practice enterprise risk management.



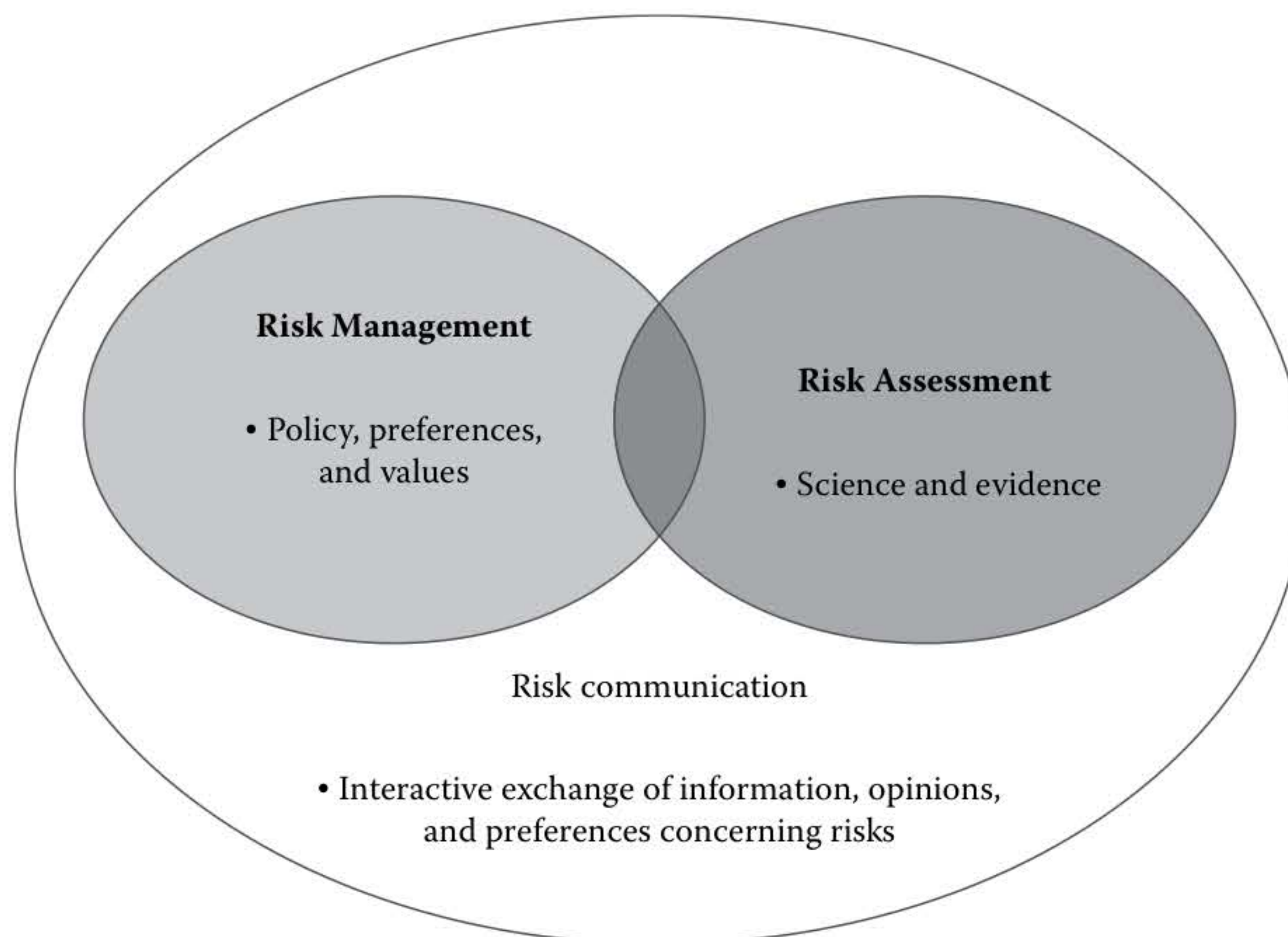
### PILLARS OF RISK ANALYSIS SCIENCE

1. The Scientific Basis
2. Concepts
3. Risk Assessment
4. Risk Perception and Communication
5. Risk Management
6. Solving Real Risk Problems and Issues

*Source:* Aven (2018).

The traditional scientific method is often not applicable for decision making, especially when uncertainties are large and social values are prominent. Risk analysis is a process for decision making under uncertainty that consists of three tasks: risk management, risk assessment, and risk communication, as shown in [Figure 1.1](#). We can think of it as the process of examining the whole of a risk by assessing the risk and its related relevant uncertainties for the purpose of efficacious management of the risk, facilitated by effective communication about the risk. It is a systematic way of gathering, recording, and evaluating information that can lead to recommendations for a decision or action in response to an identified hazard or opportunity for gain.

Risk analysis for real world problems is not pure science; it is not certain; it is not a solution; it is not static. We may be uncertain about one or more aspects of the consequence of the risk(s) of concern to us or its likelihood of occurring.



**FIGURE 1.1** Three tasks of risk analysis.



More troubling, we may be unsure of what to do about the risk or how effective our risk management efforts will be. Risk analysis should address all these things as a paradigm for decision making under conditions of uncertainty. Thus, we draw a distinction between the science of risk analysis that advances the field and the risk analysis paradigm that is applied to real world problems.

I speak the dialect of the community of practice (CoP) that raised me in risk. That would be the public sector, with stewardship responsibilities for public health and safety and natural resources. If your CoP prefers to use risk management as the overarching term to organize and label its risk work, I honestly believe you can substitute risk management for risk analysis without doing any significant harm at all to the discipline of risk. Do not let that distinction get in your way of learning. Risk management takes center stage as an organizing concept in the chapter on enterprise risk management.

People tend to not be terribly analytical when making decisions. Human reasoning is fallible. Risk analysis influences our thinking by making it more analytical. This simultaneously limits the “damage” our fallible human reasoning can inadvertently do when making decisions. Risk analysis is a useful and an evolving way to think about and solve risky and uncertain problems. It is “science-based” decision making. This is true in part because the uncertainty is sometimes substantial, but also because risk analysis honors social values. In fact, it is not a stretch to think of risk analysis as the decision-making interface between science and values.

What makes risk analysis a science and a paradigm? That question will be answered in some detail throughout this book. But let’s consider a few features that distinguish it.

First, it is based on good science. Scientific facts, evidence, and good analytical techniques are hallmarks of risk analysis. In best practice, risk analysis relies on the best available science. Risk analysis separates what we know (the science) from what we don’t know (the uncertainty), and it focuses appropriate attention on what we don’t know and how that might affect decision outcomes and, therefore, the decision itself. It aspires to get the right science into the decision process and then to get that science right. The risk assessment task is always based as much as possible on sound evidence, whether that evidence is qualitative or quantitative, known with certainty or shadowed by uncertainty. Done well, risk analysis uses the best available analytical techniques and methods.

Second, risk analysis considers social values. As important as science is, it is not the sole basis for decision making. Social values enter the risk analysis process through the risk management task. Risk analysis incorporates both good science and social values when making decisions under uncertainty.

Third, risk analysis addresses uncertainty explicitly. Few, if any, decisions are ever made with complete information and certainty. Lacking complete information and facing sometimes considerable uncertainty rarely absolves us of the need to make a decision. Risk analysis has evolved explicitly for these kinds of decision problems. It is a paradigm that copes well with soft data and that tolerates ambiguity both in



analysis and decision making. Risk assessors address uncertainty in the assessment of risks, risk managers address it in their decision making, and risk communicators convey its significance to interested parties as appropriate.

Fourth, the purpose of this paradigm is to begin to make good decisions by finding and defining the right problem. If the problem is not properly identified, little that follows will aid a successful solution. Risk analysis seeks the needed information from a variety of sources. In the process of doing so, it involves many people in its efforts to identify and resolve that which we do not know about the problem.

Fifth, because of its focus on uncertainty, risk analysis is well suited to continuously improving decisions. As uncertainty is reduced over time and problems are better understood, new and better solutions may come into view. Risk analysis is flexible and can be updated. Every risk management decision is conditional on what is known and what is not known at the time the decision is made. Risk analysis has an eye on uncertainty, and this enables it to deal with a future-focused vision of the next solution as well as the current one. Reducing that which is not yet known about a situation and ever-changing social values ensures that many risk management decisions are part of an evolutionary decision-making process.

Risk analysis provides information to decision makers; it does not make decisions. It is neither a magic bullet, nor a black box. The risk analysis paradigm helps establish the balance between the expediency of decision making and having all the information. It does not remove subjectivity and judgment from decision making. If anything, it shines a light on these things and forces us to consider what is not known with certainty.

Risk analysis is defined here as a process with three tasks. These tasks are discussed in considerable detail in subsequent chapters. For now, let us content ourselves with some informal characterizations of these tasks.

### **1.3.1 RISK MANAGEMENT**

Risk management is a process of problem identification, requesting information, evaluating risks, and initiating action to identify, evaluate, select, implement, monitor, and modify actions taken to alter levels of unacceptable risk to acceptable or tolerable levels. The goals of risk management are often said to include scientifically sound, cost-effective, integrated actions that reduce risks while taking into account economic, environmental, social, cultural, ethical, political, and legal considerations. More informally, risk management is the work one has to do to pose and then answer the following kinds of questions:

1. What's the problem?
2. What information do we need to solve it, that is, what questions do we want risk assessment to answer?
3. What can be done to reduce the impact of the risk described?
4. What can be done to reduce the likelihood of the risk described?
5. What are the trade-offs of the available options?
6. What is the best way to address the described risk?
7. Is it working? (Once implemented)



Risk management is discussed at length in [Chapter 3](#) and a description of enterprise risk management is provided in [Chapter 6](#).

### REWARDS

When the definition of risk is expanded to include uncertain potential gains, it challenges the conventional language. In particular, risk management must include modifying risks as well as mitigating them. Some of the informal questions posed must be altered somewhat.

- What's the opportunity?
- What information do we need to attain it, that is, what questions do we want risk assessment to answer?
- What can be done to increase the positive impact of the opportunity risk described?
- What can be done to increase the likelihood of the desired outcomes?

The other questions remain the same for either risk of loss or opportunity risk.

The alternating emphasis on potential gains could become tedious and cumbersome if constantly continued. Alternative discussions of potential gains will be restricted to only the most critical topics. If you find the language confusing at times, for a potential gain it may help to consider failure to attain the gain as a loss.

### 1.3.2 RISK ASSESSMENT

Risk assessment is a systematic process for describing the nature, likelihood, and magnitude of risk associated with some substance, situation, action, or event that includes consideration of relevant uncertainties. Risk assessment can be qualitative, quantitative, or a blend (semiquantitative) of both. It can be informally described by posing and answering the following questions that build on the Kaplan and Garrick triplet (1981):

1. What can go wrong?
2. How can it happen?
3. What are the consequences?
4. How likely is it to happen?

### 1.3.3 RISK COMMUNICATION

Risk communication is the open, two-way exchange of information and opinion about risks intended to lead to a better understanding of the risks and better risk management decisions. It provides a forum for the interchange of information with



all concerned about the nature of the risks, the risk assessment, and how risks should be managed. Risk communication may be informally characterized by its own set of questions (Chess and Hance 1994):

1. Why are we communicating?
2. Who are our audiences?
3. What do our audiences want to know?
4. How will we communicate?
5. How will we listen?
6. How will we respond?
7. Who will carry out the plans? When?
8. What problems or barriers have we planned for?
9. Have we succeeded?

#### **1.3.4 RISK SEMANTICS**

Even a brief review of the literature will reveal a staggering range of definitions for these tasks. As with the definitions of risk, the discipline of origin and the nature of the risk have a powerful influence over the words used to define these tasks. However, once the words are distilled to their essence, the ideas represented by the questions above capture the spirit of most definitions in use today. The differences are, in my opinion, more semantic than substantive, but semantics are very important to some people. Any good risk analysis approach will identify hazards and opportunities, characterize the risks, recognize and address uncertainty, summarize conclusions, recommend options, and document the basis for all recommendations and decisions.

### **1.4 WHY DO RISK ANALYSIS?**

In a word, “uncertainty” is the reason we do risk analysis. There is very little in life that is risk free, and risk is everywhere. Even in a certain world, decision making would not be a seamless process. We would still argue values, priorities, and trade-offs, for example; but it would be much easier than it is now. In the uncertain world in which we live, the circumstances of our lives, the problems we face, and the evidence we need, as well as the outcomes of our decisions are often unknown. We have come to realize the value found in managing, assessing, and communicating about risks to make better decisions and to better inform the affected public and stakeholders about the nature of the risks they face and the steps we take to manage them.

There are also other compelling reasons. Our decision-making processes and approaches to problems used in the past have paid amazing dividends. We have done much to make the world less risky through modern medicine, engineering, finance, environmental management, and the like. Even so, substantial and persistent problems remain. New risks appear all the time. Clearly, as well as our decision processes have served us in the past, they have not been sufficient to rid the world of risks. So, we do risk analysis to intentionally make our lives less risky, to wisely take risks when warranted and, hopefully, to reduce unacceptable risks to levels that we can at least tolerate.



Traditional approaches to decision making have relied on such things as precedent, trial and error, expert opinion, professional judgment, compromise, safety assessment, standards, precaution, inspection, zero tolerance, ignorance, and a host of other somewhat structured decision-making strategies. These traditional approaches have proven insufficient, as recurring problems and unrealized opportunities persist. They have been unable to detect and resolve many current problems. They have been slow to effectively deal with the growing complexity and rapid pace of change in society. Few of these traditional approaches have effectively integrated science and social values in decision making. They do not deal especially well with uncertainty.

Science-based risk analysis activities have been shown to be effective in reducing risks, and they are becoming the standard operating procedure for many public- and private-sector organizations. Risk analysis adds value to decisions by improving the quality of our thinking before a decision is made. Uncertainty is ubiquitous, and every organization develops its own culture of uncertainty. At one extreme, this culture is dominated by risk analysis; at the opposite extreme, we are oblivious to what we do not know. Intentionally considering the relevant uncertainty in a decision problem improves decision making.

One of the principal reasons we do risk analysis is to help provide and ensure a safer living and working environment for people. Risk analysis has also been used extensively to help protect animals, plant life, ecosystems, infrastructure, property, financial assets, and other aspects of modern society. Risk analysis has become essential to economic development. The Technical Barriers to Trade (TBT) and Sanitary Phytosanitary (SPS) Agreements of the World Trade Organization, for example, establish risk assessment as a legitimate means for establishing protective trade practices when the life, health, and safety of a sovereign nation's people are at risk. Risk analysis and risk assessment are being used more and more frequently by domestic and international organizations.

## **1.5 WHO DOES RISK ANALYSIS?**

Many risk analysis practices have been around for centuries. However, it is only in the last half century or so that the practice of risk analysis has started to become more formalized and structured. Government agencies use risk analysis as the basis for regulation, resource allocation, and other risk management decisions. Private industry, sometimes following government's lead and sometimes leading government, is also making more frequent and widespread use of risk analysis, although it may be more common for them to refer to the overarching concept as risk management. To understand who is using risk analysis it is helpful to begin with a brief history of its evolution.

### **1.5.1 A BRIEF HISTORICAL PERSPECTIVE ON RISK ANALYSIS**

Risk analysis was not possible until we were able to think intentionally about the facts of what can go wrong, how it can happen, its consequences, and the probabilities of those consequences occurring. Anyone who wants to know the history of risk analysis needs to read *Against the Gods: The Remarkable Story of Risk* (Bernstein 1996).



If there is not time to read this book, then read Covello and Mumpower's (1985) *Risk Analysis and Risk Management: An Historical Perspective*. These are simply the best single works of their genres done on the subject. This section owes a great debt to each.

We have always faced problems and have solved them, more or less successfully, since we have walked the planet. The authors cited in the previous paragraph detail this history delightfully. It was the possibility of risk assessment, however, that opened the door for risk analysis, and risk assessment has been made possible by the confluence of many events throughout history. These include the development of probabilistic thinking, which enables us to thoughtfully consider the "chance" dimension of risk, and the evolution of science, which enables us to analyze and understand the "undesirable outcomes" that can occur. Our ability to think about and to understand probability and consequences in risk scenarios made risk assessment possible.

The rise of decision sciences, especially in the last century, has enhanced the role of the manager in the analysis of risk. Our growing interest in finding effective ways to deal with uncertainty in the universe has magnified the importance of both the assessment and management tasks. The fact that we still face many old as well as a growing number of new and emerging problems not solved by our old decision-making paradigms has opened the door for risk analysis at this point in time. Growing emphasis on the involvement of the public and stakeholders in public policy decisions has created a role for risk communication. So, let us begin a brief look at the historical development of our ability to think about probability and the development of scientific methods to establish and demonstrate causal links and connections between adverse effects and different types of hazards and activities.

Undoubtedly, risk assessment began when some unknown *Homo sapiens* picked up something, ate it, fell sick, and died. "Don't eat that!" must have been the mental note all those around him made. Risk analysis had begun.

History is filled with scientific footnotes that suggest aspects of risk assessment. The Asipu in 3200 BCE (Covello and Mumpower 1985) plied the Tigris-Euphrates Valley offering guidance for risky ventures. Centuries later, Hippocrates (460–377 BCE) studied the toxicity of lead. Socrates (469–399 BCE) experienced the risks of hemlock, and Aristotle (384–322 BCE) knew that fumes from charcoal could be dangerous. Pliny (23–79 CE) and Galen (131–201 CE) explored the toxicity of mercury in their medical studies. The point being, we humans have long been engaged with aspects of risk, especially identifying those things that can do us harm.

Fast forward to the later Renaissance period in Europe where gambling, always a popular pastime, piqued an interest in the more formal study of probability. If anyone succeeded in figuring out the odds of various games of chance, it was not documented until Girolamo Cardano (1500–1571) wrote *Liber de Ludo Aleae* (Book on Games of Chance). This is one of the earliest works to explore statistical principles of probability. His book, which focused on chance, is the first to express chance as a fraction. Odds began to appear soon after.

Blaise Pascal's (1623–1662) wager is broadly considered to be one of the first examples of decision science. Pascal undertook the age-old question of God's existence: God is, or God is not? Which way should we incline, and how shall we



live our lives? Considering two states of the world (God is, God is not) and two alternative behaviors (live as a Christian, live as a pagan), Pascal used probability and concluded that the expected value of being a Christian outweighed the expected value of paganism.

The use of basic statistics is also relatively new to humans. John Graunt (1620–1674) undertook a study of births and deaths in seventeenth-century London to learn how many people may be available for military service. He used raw data in new ways, including sampling and statistical inference, that formed the basis for modern statistics. He published his famous life expectancy tables in 1662 and changed data analysis forever.

Risk management made a formal appearance in Edward Lloyd's 1687 London coffeehouse. By 1696, Lloyd's list of ship arrivals and departures along with conditions abroad and at sea was a risk management standard for everyone in the British maritime industry. Ships' captains compared notes on hazards in one corner of the coffeehouse, and it grew into the headquarters for marine underwriters, a precursor of the modern insurance industry. Flower and Jones (1974) report that London's insurance industry would help protect you from house-breaking, highway robbery, death by gin-drinking, death of horses, and would provide assurance of female chastity—no doubt the great risks of the day!

Jacob Bernoulli (1654–1705) began to integrate ideas about information and evidence into the growing body of thought on probabilities. He noted we rarely know a probability before an event (*a priori*) but can often estimate a probability after an event (*a posteriori*). This, he noted, implies changing degrees of belief as more information is compiled; so, the past is only part of reality. Thomas Bayes (1701–1761) extended this work and wrote of using new information to revise probabilities based on old information. The world was beginning to discover tools and to think that perhaps uncertainty can be measured and variability described. Many others, Laplace, Chebyshev, Markov, von Mises, and Kolmogorov, to name a few, followed, and the quantitative universe was gradually being revealed.

Meanwhile, our knowledge of disease and our powers of scientific observation were also making great leaps. Edward Jenner (1749–1823) observed that milkmaids got cowpox but not smallpox. John Snow (1813–1858) figured out that cholera was transmitted by contaminated water, by studying what today we might call a GIS (geographic information system) map of a cholera outbreak. The microscopic world was beginning to come into focus.

The Industrial Revolution marked a change in the public sector's role in the management of risks. Concerns about occupational disease and the need to protect workers and the public from toxic chemicals gave rise to the field of public health. Toxicology was one of many emerging sciences, and the idea of a "no observed adverse effects level" (NOAEL) was born in the twentieth century. This is the dose of a chemical at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control. This was clearly a firm step in the direction of risk analysis, combining science with a value judgment.

Early efforts to determine a safe level of exposure to chemicals were based on laboratory animal tests to establish a NOAEL. To leap the uncertain hurdles of



extrapolating from animals to humans and from the high doses of a chemical given to animals to the low doses to which humans were exposed, the scientific community approximated a safe level by dividing the NOAEL by an uncertainty or safety factor to establish the acceptable daily intake (ADI):

$$\text{ADI} = \text{NOAEL} / \text{uncertainty factor} \quad (1.2)$$

In the 1950s, the U.S. Food and Drug Administration (FDA) used a factor = 100 to account for the uncertainty.

More formal notions of risk were finding their way into the public-sector mentality. The Delaney Clause was a 1958 amendment to the Food, Drug, and Cosmetic Act of 1938 that was an effort to protect the public from carcinogens in food. It is often cited as an effort to establish a zero tolerance for policy purposes. When scientific methods were a bit cruder than they are now, it was easier to equate an inability to detect a hazard with a notion of zero risk.

As science improved, it became clear that zero risk was not a policy option, and the notion of *de minimis* risk took root. A *de minimis* risk is a risk so low as to be effectively treated as negligible. Mantel and Bryan (1961) suggested that anything that increases the lifetime risk of cancer by less than 1 in 100 million was negligible. The FDA later relaxed this to 1 in 1 million. The EPA proposed to adopt a uniform “negligible risk” policy for all carcinogenic residues in food in 1988. The Occupational Safety and Health Administration (OSHA) regulated all carcinogens in the workplace to the lowest level feasible. The point to be taken for our purposes is that society was beginning to get used to the idea that we would have to live with some nonzero level of risk.

Risk assessment per se began with radiation biology in the middle of the twentieth century. The Japanese survivors of World War II atomic bomb blasts made the dangers of radiation eminently clear. This new technology raised concerns about how the incidence of human cancer is influenced by exposure to small doses of radiation.

The National Academies of Science (NAS) in the United States struggled with this radiation question, and the first formal risk assessment, “Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants,” NUREG 75/014, better known as the Rasmussen Report, was prepared for the Nuclear Regulatory Commission (Nuclear Regulatory Commission, 1975). This was, among other things, a study of core meltdowns at nuclear power plants that used a no-threshold model to estimate cancer deaths following a nuclear reactor accident.

### NATIONAL FLOOD PROGRAM

Risk analysis was creeping into the public consciousness in a number of ways, although no one called it by that name at the time. In 1936, the U.S. government passed the Flood Control Act of 1936, which established a national flood control program. This program assesses, communicates, and manages risk. Following hurricanes Katrina and Rita, the U.S. Army Corps of Engineers renamed this program Flood Risk Management.



Government agencies eventually began doing risk assessment routinely, and the early pioneers of risk assessment describe a rather ad hoc process. In the 1980s the National Research Council was asked to determine whether organizational and procedural reforms could improve the performance and use of risk assessment in the federal government. In 1983 they published their response, *Risk Assessment in the Federal Government: Managing the Process*, better known as *The Red Book* because of its cover (National Research Council, 1983). This is one of the seminal publications in risk assessment, and it identifies the four steps of risk assessment as:

1. Hazard identification
2. Dose-response assessment
3. Exposure assessment
4. Risk characterization

This has been the foundation model for risk assessment that has been modified and evolved many times since.

Risk assessment came before the U.S. Supreme Court in two cases during the Carter administration. The Industrial Union Department, *AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980) case considered whether quantitative cancer risk assessments could be used in policy making. One federal agency, OSHA, said no, while the EPA and FDA said yes. The majority opinion established that risk assessment is feasible and that OSHA must do one before taking rule-making action to reduce or eliminate the benzene risk. Later, in the *American Textile Manufacturers Institute v. Donovan*, 452 U.S. 490 (1981) case, the Supreme Court reaffirmed the Benzene case finding and added that safe does not mean zero risk. With this last hurdle cleared, risk assessment moved more confidently into the government's policy arena.

Internationally, risk assessment was also growing in credibility. The General Agreement on Tariffs and Trade's (GATT) Uruguay Round on multilateral trade negotiations (1986–1994) was instrumental in the global spread of risk analysis. Specifically, two agreements—on Sanitary and Phytosanitary Measures (SPS) and on Technical Barriers to Trade (TBT)—paved the way for risk assessment in the World Trade Organization (WTO).

### THREE SISTERS

The SPS agreement has influenced the international standards of the *Codex Alimentarius* (for food), the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC), all of whom have adopted risk analysis principles for their procedures.

The SPS agreement (1995) recognizes the right of governments to protect the health of their people from hazards that may be introduced with imported food by imposing sanitary measures, even if this means trade restrictions. The agreement



obliges governments to base such sanitary measures on risk assessment to prevent disguised trade protection measures.

Following the lead of the WTO, many regional trade agreements, including the North American Free Trade Agreement (NAFTA), incorporate risk analysis principles into their agreements. Both the Food Agricultural Organization (FAO) and the World Health Organization (WHO), two United Nations agencies, lend extensive support to the use of risk analysis principles globally.

The Committee of Sponsoring Organizations of the Treadway Commission (COSO) published its “Enterprise Risk Management—Integrated Framework” in 2004. It defined enterprise risk management (ERM) as a “...process, effected by an entity’s board of directors, management, and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.” The International Organization for Standardization undertook an effort to write a new global guideline for the definition and practice of risk management internationally. That guideline “Risk Management—Principles and Guidelines” was completed and released in 2009 (ISO 31000). It was updated in 2018.

In recent years many nations have begun to make extensive use of risk analysis in their regulatory and other government functions. Risk analysis is now well established in both the private and public sectors around the world.

### 1.5.2 GOVERNMENT AGENCIES

Government agencies are widely adopting risk analysis principles to varying extents. Some agencies have begun to redefine their missions and modes of operation in terms of risk analysis principles. Risk analysis has become their *modus operandi*. Other agencies have added risk analysis principles to their existing methodologies and tools for accomplishing their mission (see accompanying text box). *Risk-informed decision making* is a term often used to describe the use of risk analysis in some government agencies. States and local governments are adopting risk analysis approaches at varying rates. Natural and environmental resource agencies as well as public health and public safety agencies tend to be the first to adapt risk analysis principles at the nonfederal levels of government.

Internationally, risk analysis has proliferated in some communities of practice. Food safety, animal health, plant protection, engineering, and the environment are some of the areas in which other national governments are likely to have established the practice of risk analysis. The global economic recession that began in 2008 has propelled economic and financial regulatory agencies to move more aggressively toward risk analysis in the form of ERM.

In 2016, the U.S. Office of Management and Budget Circular No. A-123, *Management’s Responsibility for Enterprise Risk Management and Internal Control*, established the requirement for U.S. government agencies to implement an ERM capability in order to improve mission delivery, reduce costs, and focus corrective actions toward key risks.



Risk Management Agency (Department of  
Agriculture)

<http://www.rma.usda.gov/>

Securities and Exchange Commission (SEC)

<http://www.sec.gov/>

Superfund Basic Research Program

[http://www.niehs.nih.gov/research/supported/  
sbrp/](http://www.niehs.nih.gov/research/supported/sbrp/)

Tennessee Valley Authority

<http://www.tva.gov/>

### 1.5.3 PRIVATE SECTOR

The insurance industry may represent the oldest and most explicit application of risk management in the private sector. As early as 1955, Dr. Wayne Snider, University of Pennsylvania, suggested “the professional insurance manager should be a risk manager.” By 1966, the Insurance Institute of America had created a credentialed position called “Associate in Risk Management.” In 1975, the American Society of Insurance Management changed its name to the Risk and Insurance Management Society (RIMS). In 1986, the Institute for Risk Management in London began a program of continuing education that looked at risk management in all its aspects. GE Capital used the title “Chief Risk Officer” to describe an organizational function to manage all aspects of risk that same year.

During the 1990s, several national standards began advocating that businesses should manage all risks as a portfolio across the enterprise. COSO’s “Enterprise Risk Management—Integrated Framework” was a significant step forward. By the time ISO 31000 was published in 2009, the private sector had two popular models of risk management to follow. Both of these models include the three risk analysis tasks of risk management, risk assessment, and risk communication, to varying extents. The private financial sector has also been an innovator in risk-related areas. Security has taken on a growing number of risk applications as technology has expanded the notion of and need for risk analysis. Academia has also embraced risk management in significant numbers.

Risk management spread from the insurance and financial sectors to other safety-oriented professions and businesses like engineering, construction, and manufacturing, where safety assessments have long been a part of the industry. From there it has been a short leap to every kind of private entity. Organizations in all industries have now begun a more explicit consideration of risk.

A conspicuous example of this is found in the food industry, where all links in the food chain have been devoting increased attention to food-safety risk analysis. The medical community is also increasingly involved with risk reduction. Formal risk analysis/risk management has been penetrating the private sector in increasingly large numbers. ISO 31000 marks a landmark effort to standardize many risk management notions for industry. As public policies increasingly reflect the influence of risk analysis, it is inevitable that the private-sector interest will continue to grow. A 2016 survey of more than 300 U.S.-based executives (Deloitte, 2017)



identified the following top-rated risk management successes in private industry (% of respondents):

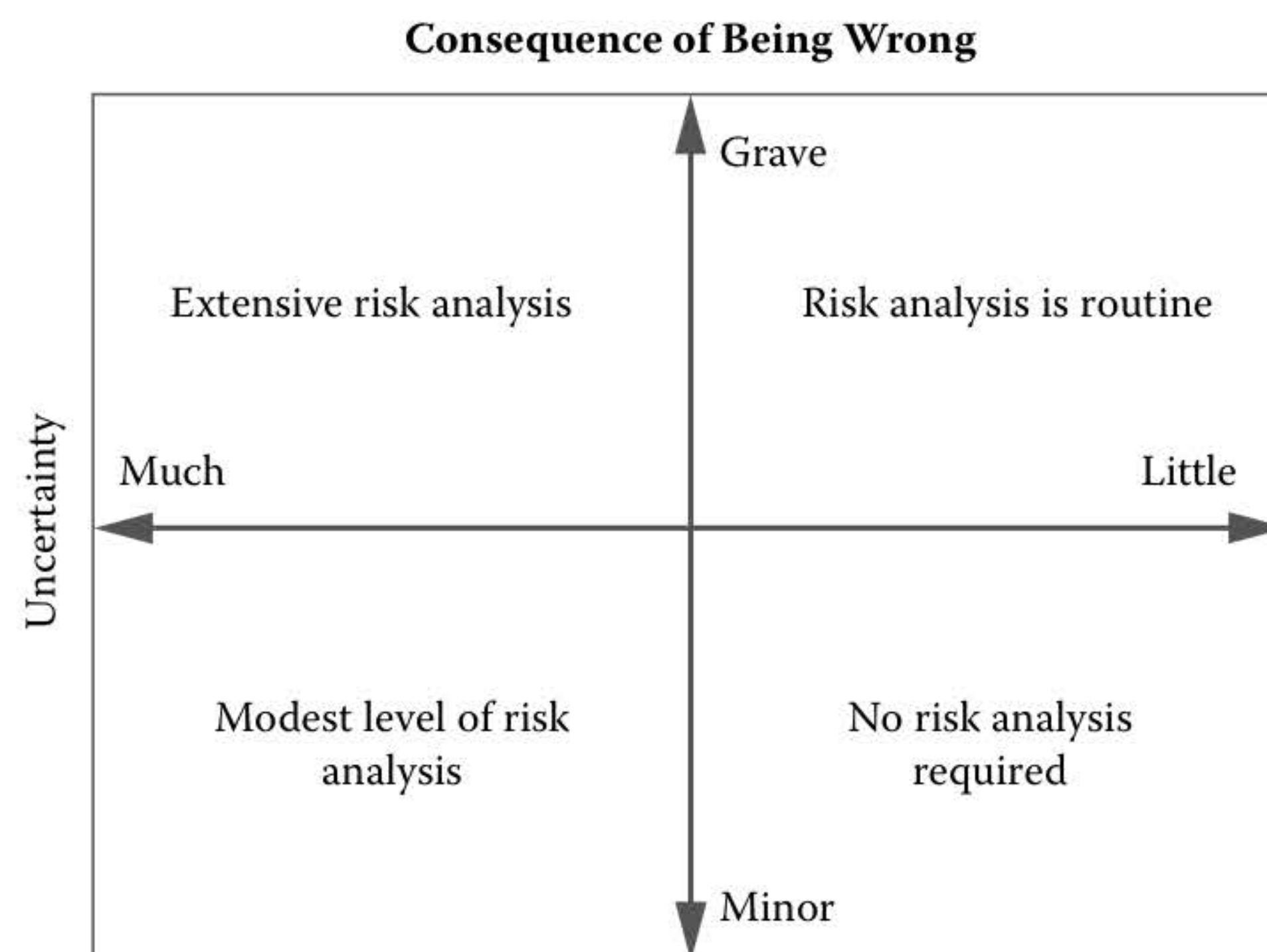
- Avoided major compliance failures (44%)
- Expanded our senior leadership team's participation in setting risk management priorities (42%)
- Have become more agile through risk management (36%)
- Identified and acted on an important opportunity for a new product or line of business (31%)
- Avoided major damage to reputation (31%)
- Improved risk management by implementing new methods/technologies (28%)
- Avoided a major potential financial loss (21%)
- Substantially improved relationships with one or more customers (19%)

With these kinds of results, the spread of risk management is inevitable.

## 1.6 WHEN SHOULD WE DO RISK ANALYSIS?

Risk analysis is for organizations that make decisions under conditions of uncertainty. [Figure 1.2](#) provides a schematic illustration of the kinds of decision contexts where risk analysis adds the most value to decision making. This value depends on how much uncertainty the organization faces and the consequences of making a wrong decision.

In the lower-right quadrant, there is little uncertainty and the consequences of being wrong are minor. This kind of decision making does not require risk analysis. Any convenient means of decision making will do here.



**FIGURE 1.2** When to use risk analysis.



When there is a lot of uncertainty, but the consequences of an incorrect decision are minor, it would be sufficient to do a modest level of risk analysis. This may entail little more than sifting through the uncertainty to assure decision makers that the decision and its outcome are not especially sensitive to the uncertainties. In some instances, it may be sufficient to establish that one or the other factors of the “consequence  $\times$  probability” product is sufficiently small as to render the relevant risks acceptable.

When the consequences of making a wrong decision rise, so does the value of risk analysis. In an environment with relatively less uncertainty but with serious consequences for wrong decisions, risk analysis is valuable as a routine method for decision making. As the uncertainty grows in extent, risk analysis becomes the most valuable, and more extensive efforts may be warranted.

Some organizations would be wise to always be doing risk analysis. In fact, a slowly growing number of organizations define themselves as risk analysis or risk management organizations, meaning that what they do as an organization is manage risks, assess risks, and communicate about risks. Others use risk analysis as a framework, tool, or methodology for specific situations. Stewards of the public trust would be well advised to use risk analysis for decision making.

Risk analysis, as a way of doing business, is especially useful for organizations that have some or all of the following elements of decision making in common (adapted from National Research Council, 2009):

- A desire to use the best scientific methods and evidence in informing decisions
- Uncertainty that limits the ability to characterize both the magnitude of the problem and the corresponding benefits of proposed risk management options
- A need for timeliness in decision making that precludes resolving important uncertainties before decisions are required
- The presence of some sort of trade-off among disparate values in decision making
- The reality that, because of the inherent complexity of the systems being managed and the sometimes long-term implications of many risk management decisions, there may be little or no short-term feedback as to whether the desired outcome has been achieved by the decisions.

Every organization has its own unique reality. They have a history, a mission, personnel, resources, policies, procedures, and their own way of doing things. If you drop risk analysis science down into any organization, the context of that organization is going to affect the way the risk analysis paradigm is going to look and work. For example, there is no agreement on what applied risk science is even called, much less agreement on any one risk analysis model to be followed by the U.S. government agencies mentioned previously. In fact, it is probably fair to say that risk analysis looks different in every organization that uses it.



### WHAT IS IT CALLED?

The EPA favors risk assessment. The FDA and Food Safety Inspection Service tend to use risk analysis. The DoD leans toward integrated risk management, while the U.S. Army Corps of Engineers is transitioning from risk-informed decision making to enterprise risk management.

Take the FDA as an example. Risk analysis is vigorously pursued in several of its centers including the Centers for Food Safety and Applied Nutrition, Veterinary Medicine, Devices and Radiological Health, and Drug Evaluation and Research. Each of these defines the terms of risk analysis differently and applies the concepts in different ways and to varying extents. They have developed their own risk-related tools and techniques. This is a strength of the paradigm. It is a remarkably flexible and robust way to think about and to solve problems, so be assured there is no one best way to practice risk analysis.

## 1.7 ORGANIZATION OF BOOK

This book is organized into two broad sections. The first six chapters provide a generic introduction to the science and principles of risk analysis. The next 15 chapters provide details on how to apply these principles.

There are hundreds of very good books already in print devoted to risk analysis. Most tend to focus, relatively quickly, on a rather narrow aspect or practice of the discipline. Many are written from a particular disciplinary or topical perspective, such as engineering, finance, environment, public health, food safety, water, and so on. This book avoids a narrow focus on any one field in favor of distilling principles, integrating topics, and stressing the application of the principles in a generic fashion. Armed with this understanding the reader can return to any CoP to apply these principles.

Risk analysis can become complex. Some books can become overwhelming for those new to risk analysis because they introduce so many ideas so fast. This text focuses narrowly on the most basic principles of the emerging science of risk analysis, that is, risk, uncertainty, risk management, risk assessment, and risk communication.

Like good risk analysis, this book proceeds in an iterative fashion. Each of the next five chapters unpacks and explains important concepts introduced in this chapter. [Chapter 2](#) takes up the notion of uncertainty in more detail. Uncertainty is the primary reason for risk analysis, and its pervasiveness is what has caused the use of risk analysis to spread so quickly in recent years. It is important for risk managers, risk assessors, and risk communicators to have a sound and common understanding of uncertainty.

[Chapter 3](#) develops the risk management component and the job of the risk manager. In best practice, every risk analysis task begins and ends with risk management. The tasks of risk management are presented in a generic fashion, free from any particular preexisting risk management model. [Chapter 4](#) unpacks the risk assessment component. This is where the analytical work gets done for any risk management activity. As with the risk management chapter, the risk assessment tasks



are presented in a model free fashion. [Chapter 5](#) explores the risk communication component in greater detail. The generic tasks of both the internal and external risk communication responsibilities are presented. [Chapters 3](#) through [5](#) together describe the three elements of the risk analysis paradigm. [Chapter 6](#) introduces enterprise risk management (ERM). ERM has been adopted by a great many private sector organizations and is significantly increasing the footprint of risk analysis. ERM tends to avoid the use of the term “risk analysis” and instead uses risk management as the overarching term for this risk paradigm.

[Chapters 7](#) through [9](#) expand on the risk management task. [Chapter 7](#) emphasizes the importance of problem-identification in risk management by expanding on the nature of problems and opportunities and by offering several techniques that have proven useful in identifying them. This critical step is one of the most overlooked and underemphasized in my risk analysis experience.

[Chapter 8](#) is about brainstorming. Good risk management requires divergent thinking at various points throughout the process. Many, if not most, well-educated professionals are justifiably leery of processes, especially those that seem trendy and fashionable. When the goal is to generate ideas and different perspectives, brainstorming is a technique that works. No risk manager should be without a technique or two to draw on.

The final risk management chapter summarizes economics for risk managers. Someone is always going to care about costs. With complex decision problems, there will always be conflicting values. This chapter focuses primarily on the economic aspects of opportunity cost, trade-offs, and incentives. The ability to correctly identify all the relevant costs and to understand how trade-offs are made at the margin is an indispensable skill for risk managers in any field. The success of a risk management decision often depends, critically, on the incentive effects of the decision.

The risk assessment task is emphasized in [Chapters 10–17](#). Many essential details will be found in them. [Chapter 10](#) introduces the reader to dozens of tools and techniques that comprise the risk assessor’s toolbox. These include qualitative and quantitative tools. The subject of [Chapter 11](#) is modeling. It begins by considering different types of models and then focuses on a 12-step model-building process that can be followed for any kind of quantitative model. This section builds on the work of others and my own experience in building risk assessment models.

The next five chapters address varying aspects of probability, all essential to decision making under uncertainty. A review of basic probability concepts used by risk assessors is found in [Chapter 12](#). It presents a pragmatic distinction between the frequentist and subjectivist views of probability without taking an advocacy position. This is followed by a discussion of probability essentials, that is, where they come from and what the most important axioms and propositions are. All of this is done with an eye on why you need to know this to do risk assessment.

[Chapter 13](#) is, I hope, one of the more useful chapters in this applications part of the text. It begins by describing the different functions that can be used to present probability distribution information. The real heart of the chapter is devoted to helping risk assessors—whether experienced or inexperienced—choose the right probability distribution to represent their knowledge uncertainty or the natural variability in the world they are modeling. The method presented has been pieced together over a



number of years of experience, where at times I was the only person who cared about the distribution and at other times the acceptance of a model stood on the credibility of the distribution(s) chosen.

[Chapter 14](#) introduces the topic of characterizing uncertainty through expert elicitation with a focus on probability elicitation, a specific form of expert elicitation that is growing rapidly. One of the most common uncertainties encountered stems from a lack of data about quantities of critical interest to our risk assessments. Experts are increasingly being used to fill in gaps in dose-response curves, to estimate probabilities of failure and unsatisfactory performance, to forecast the likelihoods of future events from sea level rise to terrorist attacks, and virtually anything you can imagine. The problem is that even experts are not so reliable at estimating subjective probabilities. Thus, it is important to have a good grasp of the issues that can arise in subjective probability elicitations. That grasp can be found in [Chapter 14](#).

The Monte Carlo process may be the most commonly used approach to probabilistic risk assessment. Every good risk assessor needs to know a little about this process and how it works. [Chapter 15](#) provides the reader with a peek behind the Monte Carlo process curtain. It will also help you think about how many iterations you need and whether you should generate them using Monte Carlo or Latin Hypercube sampling techniques.

[Chapter 16](#) builds on the work in earlier chapters to present an especially useful bundle of risk assessment tools called probabilistic scenario analysis. This chapter begins by defining scenarios and describing some of the most common types used in risk assessment. It then focuses on tree structures as one of the more useful tools for structuring scenarios. Once the probability tools and techniques of the earlier chapters are layered on top of the scenario tools, the risk assessor has a very powerful suite of tools to use to assess risk.

Techniques for addressing uncertainty are woven throughout the chapters of this text. [Chapter 17](#), however, discusses sensitivity analysis, which can be described as the uncertainty “table stakes” for every risk assessment. Exploring the significance of the uncertainty encountered in a decision problem for the decision-making process through sensitivity analysis is the absolute bare minimum standard for any risk assessment. A variety of qualitative and quantitative sensitivity analysis techniques are presented or summarized.

[Chapters 18 and 19](#) focus on decision makers. [Chapter 18](#) focuses on presenting and understanding the results of a risk assessment. This content could just as easily be considered an expansion of either the risk management or risk assessment tasks. It could also be considered part of the risk communication task because communication of complex quantitative and probabilistic information to decision makers and the general public remains a substantial hurdle in the risk analysis process.

[Chapter 19](#) reverts back to an important risk management task, namely decision making under uncertainty. This might entail making a decision when some decision criteria are uncertain or could mean not knowing what to do even when the decision criteria are understood. Although it offers an overview of some decision theory approaches, it is its practical suggestions that are likely to be most useful to readers.



Chapters 20 and 21 expand on some risk communication challenges. Chapter 20 is about developing risk communication messages for the public. Beginning with a basic communication model, it quickly differentiates the challenges of communicating about risk, especially during the high-anxiety circumstances of a crisis. Message development and message mapping are introduced as useful entry points into this rich field of risk communication. Chapter 21 addresses the value of effective story telling when communicating the results of risk assessments and risk management actions. If risk analysis does not lead to effective action, then the battle is not won. Data may be effective in convincing people, but risk analysis is science in action, and it takes compelling stories not ponderous reports to inspire people to action.

The final chapter, Chapter 22, presents examples of risk assessments. Eight examples are offered to illustrate some of the ideas discussed throughout the text. Appendix A provides an introduction to Palisade Corporation's DecisionTools® Suite software that was used in the preparation of this book. Files used in the creation of this book and additional exercises as well as a free student version of the software are available at <http://www.palisade.com/bookdownloads/yoe/principles/>.

## 1.8 SUMMARY AND LOOK FORWARD

Risk is the chance of an undesirable outcome. That outcome may be a loss or the failure to attain a favorable situation. In a certain world there is no risk because every outcome is known in advance. It is uncertainty that gives rise to risk.

Safety is a subjective judgment, while risk analysis is, in principle, an objective search for the risks in any given situation. Risk analysis is the framework or, if you prefer, the science used to manage, measure, and talk about risk. It has three components: risk management, risk assessment, and risk communication. Risk analysis is now possible because of the confluence of many scientific developments. Its use in the United States and internationally is growing steadily, and applications are found in a wide variety of fields.

The language of risk analysis is evolving. It would be comforting to think that it is evolving toward some consensus definitions and a common terminology. That is not yet the case, and this book makes no attempt to resolve the language differences. What it does do is attempt to distill the principles common to the many different dialects of risk that are spoken in the fields of applied risk analysis. There is a growing tendency among some in both the public and private sectors to refer to the risk analysis paradigm as risk management. This text will use risk analysis to represent the emerging science and to describe the use of risk analysis science as applied to real world problems. Do not let that semantic debate get in the way of your understanding. Use the term you prefer.

The next chapter gets to the root cause of risk analysis, that is, uncertainty. A primary role of the risk analyst is to separate what we know from what we do not know and then to deal honestly, intentionally, and effectively with those things we do not know. The job of the risk analyst is to be an honest broker of information in decision making. Knowledge uncertainty and natural variability, two fundamental concepts essential to understanding risk analysis, are the focus of Chapter 2.



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# 2 Uncertainty

## 2.1 INTRODUCTION

Because risk analysis focuses on decision making under uncertainty, it is important to understand what uncertainty is. At the most basic level, when we are not sure, then we are uncertain. Uncertainty arises at two fundamentally different levels. First, there is the macro-level of uncertainty. We all make decisions in a changing and uncertain decision environment. This means the systems, processes, social values, ways forward, and outcomes of concern to us may be uncertain. Second, there is the micro-level of uncertainty. This is the uncertainty that pertains to specific decision contexts and their relevant knowledge, data, and models. These latter uncertainties receive most of the attention in risk assessment.

If there was no uncertainty about facts, there would be no question about whether or when a loss would occur and how big it would be. Likewise, we would always know how an opportunity would turn out. Even so, uncertainty about what we should do in the face of these situations would still arise because of differing values. Uncertainty is the reason for risk analysis. Risk assessors have to understand uncertainty because they are, in a sense, the first responders to uncertainty. It is the assessors who identify data gaps, holes in our theories, shortcomings of our models, incompleteness in our scenarios, and ignorance about some quantities and variability in others. It is an important part of the risk assessor's\* job to address the uncertainty in individual assessment inputs.

Think of the assessor's job as separating what we know from what we do not know about a decision problem context and then being intentional about assessing the significance of the things we do not know for decision making. There are usually things we know with certainty. We can measure distances, count dollars, we know atomic structures of chemicals; our physical world is loaded with facts. But every decision problem comes with a "pile" of things we do not know. The risk assessor, along with the risk manager, has to identify that pile and what is in it.

It is the risk manager's job to decide how to handle the uncertainty that remains in decision making. Measures of decision criteria may be uncertain, the outcome of a risk management option may be unknown. Addressing these uncertainty issues is the risk manager's responsibility. There may also be uncertainty that arises with the risk management task. Even when all the decision criteria are clear, the risk manager may not know what to do because of conflicting values. This uncertainty also belongs to the risk manager. Risk managers need to understand uncertainty because they are the final arbiters of it in the decision-making process.

The risk communicator has the responsibility of understanding the uncertainty and its relevance for decision making so that they can explain it and its significance to others. That task requires risk communicators to understand input, output, and

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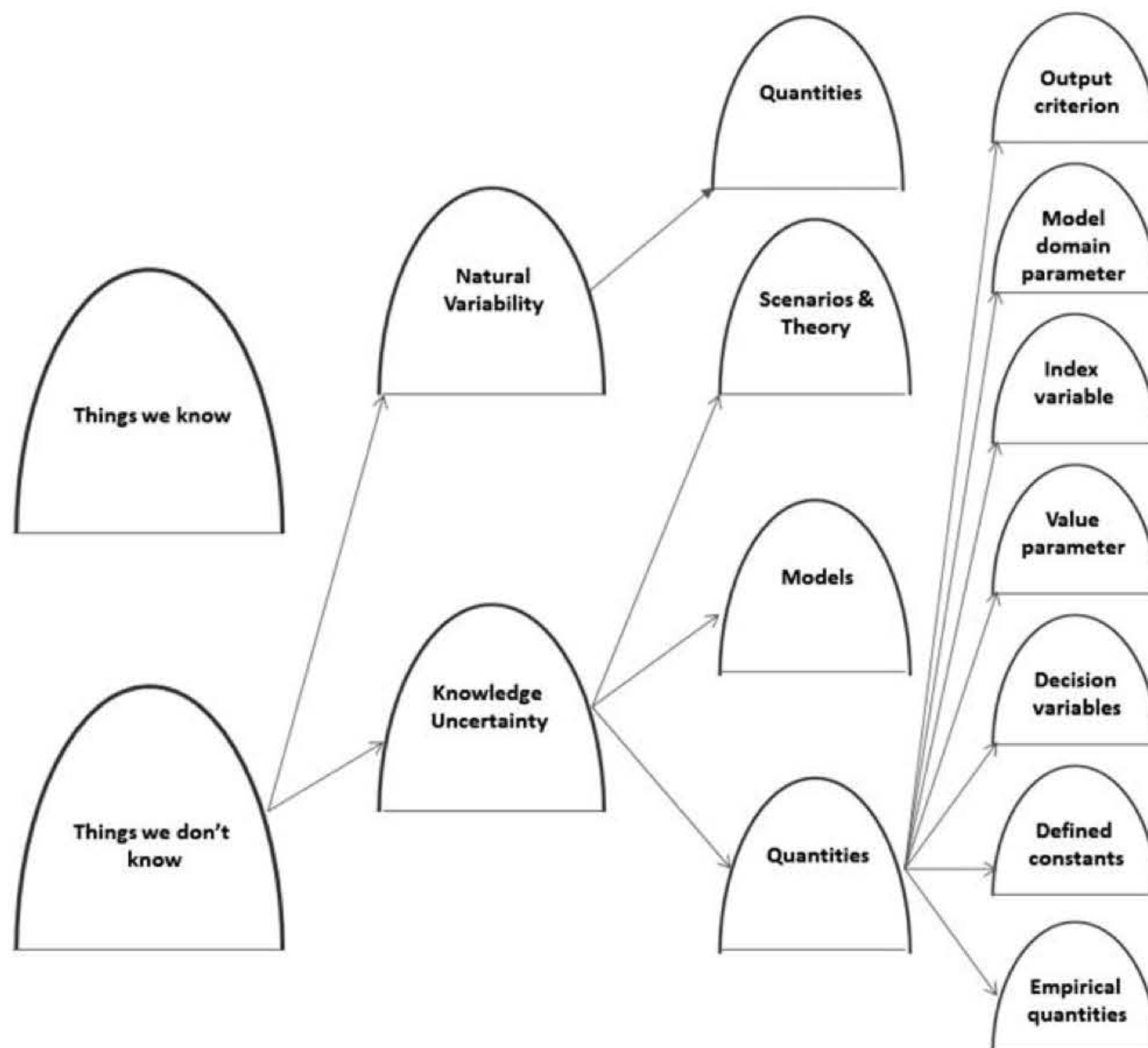
\* The possessive case used for risk assessors and risk managers will always be in the singular form for the sake of simplicity. It should be understood, however, that both can be multiple in numbers at times.



outcome uncertainty well enough to make it understandable by diverse audiences among the public and stakeholders interested in a risk management decision.

There is another important distinction to make about things that are uncertain. Uncertainty is relevant if it could impact a decision in at least a subtle way. Relevant uncertainty may make one option less appealing than another or it might make a particular stakeholder uneasy. Relevant uncertainty can be categorized as instrumental or noninstrumental. The ability to distinguish between the two is essential to both good risk assessment and good risk management. Instrumental uncertainty can alter the decision that is made or the outcome of that decision. Noninstrumental uncertainty refers to uncertainty that would not alter a decision if it was reduced. Noninstrumental holes in our data or gaps in information may be relevant in some way, but they would not affect the decision to be made if they were filled. Good risk assessors and risk managers are able to focus on identifying, reducing, or otherwise characterizing the instrumental uncertainty encountered in decision making.

This chapter focuses, in a conceptual way, on the pile of things we do not know and specifically on the instrumental uncertainty in that pile of things. In order to know how best to address the things we do not know, the assessor must first understand the nature of those things in the pile of unknowns (see [Figure 2.1](#)). The



**FIGURE 2.1** Separating what we know from what we do not know and sorting out the unknowns.



original pile of unknowns, or uncertainty, is then sorted into two distinct sources of not knowing: natural variability and knowledge uncertainty. Natural variability generally refers to empirical quantities. Knowledge uncertainty is divided into three main piles: scenarios and theory, models, and quantities. The quantities, in their turn, are separated into types of quantities first proposed by Morgan and Henrion (1990). This conceptual sorting activity enables us to choose most appropriately from the various tools, techniques, and methodologies available for addressing uncertainty in the assessment and management tasks.

This chapter begins by considering the macro-level of uncertainty that is sometimes overlooked in risk analysis. Then it focuses on the micro-level uncertainty issues that occupy so much of the risk assessor's concerns. At that point in the chapter we will reengage the structure shown in [Figure 2.1](#).

An important distinction will be drawn between knowledge uncertainty and natural variability, and the many piles illustrated in [Figure 2.1](#) will be explored and discussed. The causes of uncertainty in empirical quantities are considered to round out the discussion of uncertainty as depicted in the figure.

Before beginning we offer an important clarification of the language. People often speak of uncertain values, and this is, strictly speaking, not correct. The values themselves are not uncertain; it is the assessor and the manager who are uncertain about what a factual value is or what a value that reflects a preference should be. Even so, this text will join in the use of that terminology to avoid the repeated verbosity of explaining that these are values people are uncertain about.

## 2.2 UNCERTAINTY FROM 75,000 FEET

Uncertainty is an emerging constant in modern decision making. We all operate in an uncertain environment. Growing social complexity and an increasingly rapid pace of change are normal parts of the decision-making landscape, and they contribute a great deal to the uncertain environment in which we operate. Risk analysis offers a viable alternative to clinging to a deterministic style of decision making in this uncertain environment.

### TOP FIVE GLOBAL RISKS

#### In terms of likelihood

1. Extreme weather events
2. Natural disasters
3. Cyberattacks
4. Data fraud or thefts
5. Failure of climate-change mitigation and adaptation

#### In terms of impact

1. Weapons of mass destruction
2. Extreme weather events
3. Natural disasters
4. Failure of climate-change mitigation and adaptation
5. Water crises

*Source:* The Global Risks Report 2018.



The world grows more complex. Think of complexity, as used here, in a social sense. It refers to such things as the size of a society, the number of its parts, the distinctiveness of those parts, their interconnectedness, the variety of specialized social roles that it incorporates, the number of distinct social personalities present, and the variety of mechanisms for organizing these into a coherent, functioning whole. Augmenting any of these dimensions increases the complexity of a society (Tainter, 1996). The level of complexity in our social, economic, and technological systems is increasing to a point that is too unsettled and rapidly changing to be wholly understood or predicted by human beings.

For over 99% of human history we lived as low-density foragers or farmers in egalitarian communities of no more than a few dozen persons and even fewer distinct social roles. In the twenty-first century we live in societies with millions of different roles and personalities. Our social systems grow so complex as to defy understanding. Consequently, our systems of problem solving have grown more complex.

We face an increasingly rapid pace of change in almost every arena. Scientific breakthroughs make things that once were impossible to conceive commonplace. Much of this change is driven by rapid advances in technology. For example, the risk of conflict is exacerbated by weaponized robotics and artificial intelligence. Cyberspace is an entirely new domain for conflict. Technology changes social values and beliefs as well as the way we live and work. The ways we communicate have changed forever and continue to change in ways that are difficult to forecast. Change is too rapid and at times too turbulent to be wholly understood or predicted.

Social, economic, and technological connectivity around the globe accelerates at a dizzying pace. Social movements are often global in their pervasiveness. We are increasingly a global economy. Fashions are designed in New York and approved in London, patterns are cut in Hong Kong, clothes are made in Taiwan and shipped in containers on vessels that call around the world, and then the clothes are sold across Europe and North America. Computer viruses spread in hours; human viruses spread in weeks. We are indelibly connected.

With government deficits and debts rising in the more established economies of the world, there is relentless pressure on costs in all public decision making. Patterns of competition are becoming unpredictable. It is getting harder and harder to understand and anticipate who the competition is for a job, for U.S. grain, for land use, and so on. For businesses and government agencies alike, customer/client profiles are changing rapidly and unpredictably. We see quickly increasing and diversified customer demands. There is a growing role for one-of-a-kind services and production, and rapid sequences of new tasks in business and government are becoming more routine. A media explosion is just one of the consequences of an increase in the number and speed of communication channels. Big data is transforming the ways that businesses operate.

As a result of these and other changes, we have entered a world where irreversible consequences, unlimited in time and space, are now possible. This is or should be extremely important to risk managers in both the public and private sectors. Decades after the accident at Chernobyl, some of its victims haven't even been born yet. Some



of the wicked problems\* risk managers face can have a long latency period. Many of the United States' landscape-scale ecosystem restoration problems—like those in the Florida Everglades, Coastal Louisiana, and the Columbia River basin—as well as such global concerns as greenhouse gases, climate change, and sea level rise provide clear examples of problems that took decades to emerge and be recognized. The implications of the solutions being formulated may similarly take decades to be understood.

A new phenomenon of “known unawareness” has entered our lexicon. . In November 2006, Donald Rumsfeld summarized this truth to scattered laughter when he said: “There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we now know we do not know. But there are also unknown unknowns. These are things we do not know we do not know” (Profita, 2006). No one is laughing anymore. As a society we are beginning to realize that despite all we know, the unknown far outweighs what is known. Knowledge is as much to create more questions as it is to provide definitive answers.

Clearly, scientists now know much more about BSE (bovine spongiform encephalopathy or mad cow disease) than when it was first found in cattle in 1986. Even now, decades after the disease's discovery, its origins, its host range, its means of transmission, the nature of the infectious agent, and its relation to its human counterpart new variant Creutzfeldt–Jakob disease remain mostly unknown. We have begun to suspect that there are some risks for which there may be no narrative closure, no ending by which the truth is recovered and the boundaries of the risk established.

Although most of us live and work in nations, our interactions and our risks are increasingly global in nature. The interconnected nature of the global system produces cascading risks at the domestic level. Failing government in Syria produces civil conflict that transfers economic, social, and political pressures into neighboring countries as well as nations around the world. Terrorism threatens the lives of innocent citizens around the world. An oil spill in the Gulf of Mexico reverberates around the world. It becomes increasingly difficult to affix responsibility for problems and their solutions. Who is destroying the ozone, causing global warming, spreading BSE and AIDS? Where did the H5N1 or H1N1 viruses originate and how? Whose responsibility is it to fix these things?

Despite the world's rapid advances in all kinds of sciences, we are increasingly dominated by public perception. Public perception is a palpable force. In some situations, it is an irresistible one. Uncertainties and the risks they give rise to have a social context. Without social and cultural judgments, there are no risks. Nonetheless, these social and cultural judgments are not always grounded in fact. Unfortunately, they are also not always adequately considered in decision-making processes. The public is fond of equating the possibility of an undesirable outcome with the probability of such an outcome. This makes conceivable risks seem very possible, and it fuels our fears of the uncertain. It leads, paradoxically, to audiences that are alternately outraged and indifferent about the risks they face.

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\* Wicked problems are complex problems that lack right and wrong solutions. Instead there are many candidate solutions, and some are better and some are worse than others, but none is clearly best.



Social and cultural views can find and have found their way into public policy. This is in part because many things that were once considered certain and safe, and often vouched for by authorities, turned out to be deadly. The BSE experience in Europe, the SARS (severe acute respiratory syndrome) experience in Asia and elsewhere, the melamine contamination from Chinese products, even ordinary things like dining out or attending a concert provide vivid examples of this phenomenon. Applying knowledge of these experiences to the present and the future devalues the certainties of today. This is what makes conceivable threats seem so possible and what fuels our fears of that which is uncertain. It is also what makes criticism of a decision that masquerades as certain embarrassingly easy.

Responsibility in this more connected world has become less clear. Who has to prove what? What constitutes proof under conditions of uncertainty? What norms of accountability are being used? Who is responsible morally? Who is responsible for paying the costs? These questions plague decision makers nationally and transnationally.

We all live and operate in this uncertain reality. Social values are formed, changed, and reformed against this backdrop of macro-level uncertainty. There are so many social relationships that it is difficult to know what values the nation, a project area community, or a stakeholder group holds dear at any one point in time. Yet many organizations and individuals cling stubbornly to a deterministic approach to decision making that belies the experience of public and private sectors the world over. Decision making needs a “culture of uncertainty.” Risk analysis provides just such a culture.

The future is fundamentally unknowable. There must be recognition of the central importance of demonstrating the collective will to act responsibly and accountably with regard to our efforts to grapple with this fundamental uncertainty and the inevitable shortfalls that will occur despite every best effort to account for this uncertainty. In an uncertain world we cannot know everything, and we will make mistakes despite our best efforts to the contrary. This is the challenge that invites risk analysis to the fore.

## **2.3 THE UNCERTAINTY ON YOUR DESK**

The uncertainty that has received the most attention in risk analysis is not the macro-level uncertainty we see from 75,000 feet, nor is it the resulting uncertain environment in which we make decisions. It is the uncertainty that plagues our specific decision contexts. Anyone involved in real problem solving and decision making knows we rarely have all the information we need to make a decision that will yield a certain outcome. For any decision context, we can always make a pile of the things we know and a pile of the things we do not know. For risk analysis, we need to be able to take that pile of things we do not know and sort through it to better understand the nature and causes of the uncertainties we face. It is the nature and cause of the uncertainty that dictates the most appropriate tool to use on it. The first and most important distinction to make in our pile of unknowns is how much of the uncertainty is due to knowledge uncertainty and how much is due to natural variability.



### 2.3.1 KNOWLEDGE UNCERTAINTY OR NATURAL VARIABILITY?

You're headed for Melbourne, Australia, in November and are unsure how to pack because you do not know what the weather is like there at that time of year. For simplicity, let's focus on the daily high temperature. You do not know the mean high temperature for Melbourne in November. This is a parameter, a constant, with a true and factual value. That you do not know this fact makes the situation one of knowledge uncertainty. A true value exists and you do not know it. You are uncertain about a fact.

Suppose you learn from the Bureau of Meteorology, Australia, that this value is 21.9°C (71°F). The knowledge uncertainty has been removed. Now a new problem emerges. Even though you know the average temperature is 21.9°C, you have no way of knowing what the high temperature will be on any given day. In fact, you wisely expect the high temperature to vary from day to day.

#### DEFINITIONS OF UNCERTAINTY AND VARIABILITY

*Uncertainty:* Lack or incompleteness of information. Quantitative uncertainty analysis attempts to analyze and describe the degree to which a calculated value may differ from the true value; it sometimes uses probability distributions. Uncertainty depends on the quality, quantity, and relevance of data and on the reliability and relevance of models and assumptions.

*Variability:* Variability refers to true differences in attributes due to heterogeneity or diversity. Variability is usually not reducible by further measurement or study, although it can be better characterized.

*Source:* National Research Council (2009).

Using our very loose definition at the start of this chapter, you say you are not sure what the temperature will be on any given day, so that must be uncertainty as well. And in a very general sense it is. However, and this is an important however, this value is uncertain for a very specific, common, and recurring reason; there is natural variability in the universe.

This natural variability is usually separated out from other causes of uncertainty in order to preserve the distinction in its cause for reasons that will soon be apparent. Hence, we'd say you are no longer uncertain about the mean high temperature, but you still do not know the high temperature on any given day because of natural variability. The temperature varies from its mean day to day due to variation in the complex system that produces a high temperature each day. For a more formal distinction of these two concepts, we introduce the terms *epistemic* and *aleatory uncertainty*.

*Epistemic uncertainty* is the uncertainty attributed to a lack of knowledge on the part of the observer. It is reducible in principle, although it may be difficult or expensive to do so. Epistemic uncertainty, what was described in the previous example as knowledge uncertainty, arises from incomplete theory and incomplete understanding



of a system, modeling limitations, or limited data. Epistemic uncertainty has also been called internal, functional, subjective, reducible, or model form uncertainty. *Knowledge uncertainty* is another easier to remember and perhaps more descriptive term used to describe this kind of uncertainty. It is used throughout this book when we refer specifically to epistemic uncertainty.

Some generic examples of knowledge uncertainty include lack of experimental data to characterize new materials and processes, poor understanding of the linkages between inputs and outputs in a system, and thinking one value is greater than another but being unsure of that. Other examples include dated, missing, vague, or conflicting information; incorrect methods; faulty models; measurement errors; incorrect assumptions; and the like. Knowledge uncertainty is, quite simply, not knowing a fact. The most common example may be not knowing a parameter or value, like cost or a benefit-cost ratio, that we are interested in for model building or decision-making purposes.

### AN IMPORTANT DISTINCTION

Natural variability cannot be reduced with more or better information.

Knowledge uncertainty can be reduced with more and better information through such means as research, data collection, better modeling and measurement, filling gaps in information and updating out-of-date information, and correcting faulty assumptions.

Aleatory uncertainty is uncertainty that deals with the inherent variability in the physical world. Variability is often attributed to a random process that produces natural variability of a quantity over time and space or among members of a population. It can arise because of natural, unpredictable variation in the performance of the system under study. It is, in principle, irreducible. In other words, the variability cannot be altered by obtaining more information, although one's characterization of that variability might change given additional information. For example, a larger database will provide a more precise estimate of the standard deviation of a temperature, for instance, but it does not reduce variability in the population of daily high temperatures. Aleatory uncertainty is sometimes called variability, irreducible uncertainty, stochastic uncertainty, and random uncertainty. The term adopted for usage in this book when we refer specifically to aleatory uncertainty is *natural variability*.

Some generic examples of natural variability include variation in the actual weight of potato chips in an eight-ounce bag, variation in the response of an ecosystem to a change in the physical environment, and variation in hourly traffic counts from day to day. There is also natural variability in any attribute of a population.

*Knowledge uncertainty* and *natural variability* are terms used by the National Research Council (2009). It will be convenient to use the term *uncertainty* to encompass both of these ideas, so that is the convention adopted in this book. However, this is by no means the usual convention, and the reader is advised to always clarify, when possible, and to try to carefully discern, when it is not, what the user of these terms means from the context of their usage.

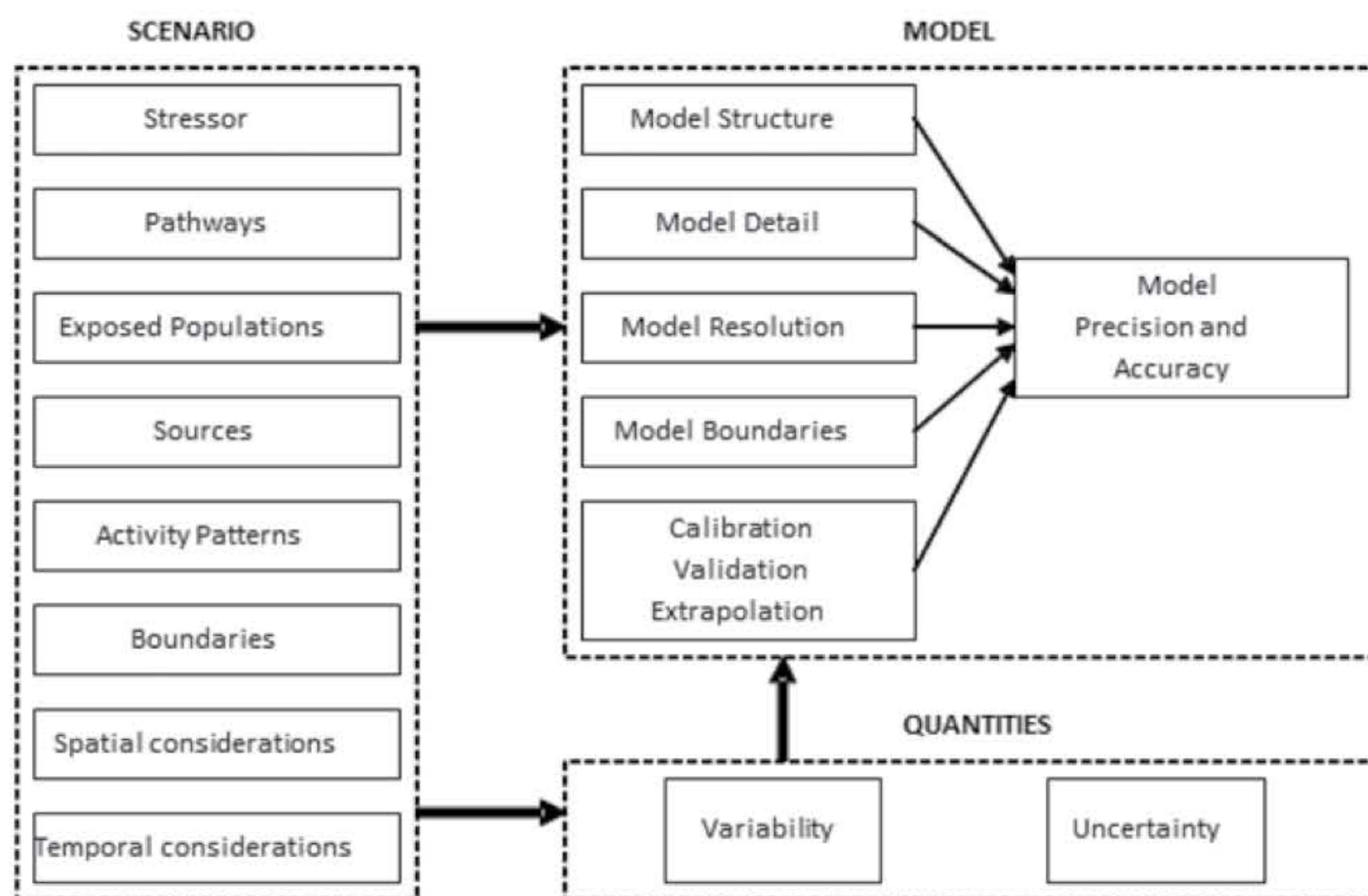


To complicate matters, reality is often messy. Returning to our Melbourne example, we can see that at the outset we are dealing with both knowledge uncertainty and natural variability. It takes experience for a risk assessor to be able to comfortably label the reasons that a value may be uncertain. It is not always possible and not always important to be able to separate knowledge uncertainty and natural variability. In general, the most important reasons for separating the effects of the two in a risk assessment are to select an appropriate tool for addressing them and to understand that devoting more resources to the risk assessment effort may reduce knowledge uncertainty, but it will not reduce natural variability. The only way to change the natural variability produced by a system is to change the system itself. This will not eliminate natural variability; it will produce a new form of, presumably, more favorable variability in the altered system. Risk assessment can reduce knowledge uncertainty. Risk management measures can alter natural variability.

### 2.3.2 TYPES OF UNCERTAINTY

To sort through and understand the nature of the things we do not know, we begin by first differentiating knowledge uncertainty from natural variability. Natural variability is most often addressed through narrative descriptions of the variability, statistics, and probabilistic methods. Natural variability tends to apply to quantities only. Knowledge uncertainty is a bit more complex and needs additional sorting. The next tier of sorting separates our knowledge uncertainty into scenarios, models, and inputs/quantities, as seen in [Figure 2.2](#).

[Figure 2.2](#) provides an example of the types of knowledge uncertainty that might be encountered. It presents an ecological risk example. For now, think of scenarios as the stories we tell about risks. These are the narratives that describe what we believe to be



**FIGURE 2.2** Sorting our knowledge uncertainty into scenarios, models, and input quantities.



true about the phenomena we study. This is where theory and knowledge of processes are most important. Models are used to give structure to scenarios and to perform calculations based on the quantities provided. Thus, we identify these three broad basic types of knowledge uncertainty you can expect to encounter in risk assessment.

Scenario uncertainty results when the elements of a scenario or their relationships are unknown or incomplete. Gaps in theory and understanding are most likely to occur in the stories we tell about what can go wrong, the consequences of it happening, how it happens, and how likely it is to happen. In the case of an ecosystem scenario, we might misunderstand the stressors that affect a habitat. Not knowing the relevant activity patterns of a locally threatened species could be another source of scenario uncertainty. We may also fail to understand all the relevant pathways in an ecosystem.

Model uncertainty reflects the bias or imprecision associated with compromises made or lack of adequate knowledge in specifying the structure and calibration (parameter estimation) of a model. Model structure typically refers to the set of equations or other functional relationships that comprise the specified scenario for the model. Model detail refers to the inclusion or omission of specific phenomena as well as the simplicity or complexity with which they are represented. Model resolution refers to the temporal or spatial scale at which information can be distinguished, for example, minutes versus hours versus years. Model boundaries describe the fidelity with which the desired scenario is captured by the model. Ideally, the precision and accuracy of the model predictions will be assessed as part of the validation exercise. In other words, how well does our model capture reality?

### KNOWLEDGE UNCERTAINTY DEFINITIONS

*Scenario uncertainty:* Uncertainty in specifying the risk scenario which is consistent with the scope and purpose of the assessment.

*Model uncertainty:* Uncertainty due to gaps in scientific knowledge which hamper an adequate capture of the correct causal relations between risk factors.

*Parameter/input uncertainty:* Uncertainty involved in the specification of numerical values (be it point values or distributions of values) for the factors which determine the risk.

*Source:* WHO (2006).

Quantity or input uncertainty is encountered when the appropriate or true values of quantities are not known (knowledge uncertainty). These quantities are of enough importance to warrant additional discussion.

### 2.3.3 QUANTITY UNCERTAINTY

The most commonly encountered uncertainty is quantity uncertainty. Quantities can be unknown because of knowledge uncertainty or because of natural variability. Morgan and Henrion (1990) offer a very useful taxonomy for those seeking to understand



the basic types of quantity uncertainty shown in [Figure 2.1](#). Before considering their taxonomy, we need to make an important distinction. Some quantities have a true or factual value, while others do not. Instead of a true value, they have a best or most appropriate value that reflects some subjective judgment. There may be significant consternation about the best or preferred value for these kinds of quantities, but they have no true value we can discover. The search for a true value is an objective one, while the search for a best value is subjective.

In general, true values are looked up, measured, or estimated by some means. The means by which quantities with true values are estimated vary, and the best choice will depend on the cause of the value's uncertainty. Best or appropriate values are varied systematically (sometimes called parametric variation or sensitivity analysis) to examine the sensitivity of the model and its outputs to different chosen values.

### TRUE VALUES

The population of a city, number of colony forming units per gram of material, percent of channel bottom that is rock, mean strength of materials in a structure, mean daily stream flow, average weight of an adult striped bass, median serving size, specificity of a diagnostic test, closing price of a stock, and contaminant concentration in a specific exposure are all quantities that have a true value.

Risk analysis can require a lot of information. Risk assessment, in particular, can involve a great deal of quantitative information that includes many parameters (numerical constants) and variables. The quantities used in risk assessment are frequently a major source of uncertainty. Having a way to think about these quantities and to talk about their uncertainty is critical to the success of any risk analysis.

Morgan and Henrion's (1990) classification of uncertain quantities includes:

- Empirical quantities
- Defined constants
- Decision variables
- Value parameters
- Index variables
- Model domain parameters
- Outcome criteria

The significance of the objective or subjective nature of the quantity uncertainty, as well as the type of quantity, will become most evident when one chooses a tool, technique, or methodology to treat the uncertainty appropriately. Look at the examples in [Table 2.1](#), then read the explanations that follow to better understand Morgan and Henrion's taxonomy of quantities. The approach used to resolve uncertainty depends very directly on what is uncertain and why it is uncertain.



**TABLE 2.1**  
**Uncertain Quantity Types and Examples**

| Types of Quantities     | Selected Examples                                                                                                                      |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Empirical quantities    | Stream flow, eggs produced daily, vehicles crossing a bridge, temperature, time to complete a task, prevalence                         |
| Defined constants       | Pi, square feet in an acre, gallons in an acre foot, speed of light, size of a city                                                    |
| Decision variables      | Acceptable daily intake, tolerable level of risk, appropriate level of protection, reasonable cost, mitigation goal                    |
| Value parameters        | Value of a statistical life, discount rate, weights assigned in a multicriteria decision analysis, user-day values                     |
| Index variable          | A particular year in a multiyear model, the location of an egg on a pallet, a geographic grid in a spatial model                       |
| Model domain parameters | Study area, planning horizon, industry segment, climate range                                                                          |
| Outcome criteria        | Mortalities, illness rates, infrastructure failures, fragility curves, costs, probabilities, benefit-cost ratios, risk-risk trade-offs |

### 2.3.3.1 Empirical Quantities

Empirical quantities are the most common quantities encountered in a quantitative risk assessment; they have a true value. Empirical quantities are things that can be measured or counted. This includes distances, times, sizes, temperatures, statistics, and any sort of imaginable count. They have exact values that are unknown but measurable in principle, although it may be difficult to do so in practice. A full range of methods from narrative descriptions through probabilistic methods are suitable for addressing uncertainty in these quantities.

### 2.3.3.2 Defined Constants

Defined constants have a true value that is fixed by definition. When these values are not known by the analyst, for example, you might not know how many square feet are in an acre or how many gallons of water in an acre-foot of water, these quantities can end up in the pile of things we do not know. Defined constants provide the perfect opportunity to point out the importance of understanding the nature of your unknowns. When you do not know one of these quantities, you do not use sensitivity analysis or probabilistic methods; instead you look them up. There are 43,560 square feet in one acre and 325,851 gallons of water in one acre-foot of water.

### DECISION RULE UNCERTAINTY

What is the best endpoint for your purposes? Imprecise or inappropriate operational definitions for desired outcome criteria, for example, “risk” can be a subtle problem.



Concerned about a public health risk? Should you use the number of exposures, infections, illnesses, hospitalizations, or deaths? Which is a better criterion to base a decision on: lifetime mortality risk, annual risk of mortality, risk to children or other subpopulations, or something entirely different?

Concerned about an economic issue? Should you maximize net benefits or minimize costs? Do you want to maximize market share or profits?

There is no right answer to these questions, only better or worse ones. Someone must decide what the decision criterion or rule will be to resolve this uncertainty.

#### **2.3.3.3 Decision Variables**

This is a quantity which someone must choose or decide. Decision makers exercise direct control over these values; they have no true value. The person deciding this value may or may not be a member of the risk analysis team, depending on the nature of the variable. Policy makers may determine the values of some decision variables to ensure uniformity in decision making. An agency may decide it is unacceptable to increase the lifetime risk of cancer by more than  $10^{-6}$ , for example. Thus, decision variable values are sometimes set by decision makers external to the risk analysis process.

In other instances, risk analysis team members may make these decisions. Examples could include determining a tolerable level of risk or design characteristics of risk management options that differentiate one option from another. Decision variables are subjectively determined. Uncertainty about them is most appropriately addressed through parametric variation and sensitivity analysis.

#### **2.3.3.4 Value Parameters**

These values represent aspects of decision makers' preferences and judgments; they have no true value. They are subjective assessments of social values that can describe the values or preferences of stakeholders, the risk manager, or other decision makers. Like decision variables, some of them may be decided by those external to the risk analysis team, while others are decided by team members.

Social values, like the monetary value of a statistical life or society's time preferences for consumption, are likely to be established corporately to ensure uniformity in decision making. Establishing decision-specific values, like assigning relative weights to different decision criteria, may be set by the team. Uncertainty about value parameters is most appropriately addressed through parametric variation and sensitivity analysis.

#### **2.3.3.5 Index Variables**

Index variables identify elements of a model or locations within spatial and temporal domains; they may or may not have a true value. Bacterial counts "24 hours after" yolk membrane breakdown, costs "ten years after" implementing a risk management solution, water quality at a cove, and defining the age and gender of a representative individual are examples of index variables. If a very specific point in time or place in space are desired, there may be a true value. Random or representative choices of index variables do not have true values and are subjectively determined: should we



look at future conditions in five years or ten? Uncertainty in index variables is most appropriately addressed through parametric variation and sensitivity analysis.

#### **2.3.3.6 Model Domain Parameters**

These values specify and define the scope of the system modeled in a risk assessment. They describe the geographic, temporal, and conceptual boundaries (domain) of a model. They define the resolution of its inputs and outputs; they may or may not have true values. Scale characteristics are chosen by the modeler and most often have no true value in nature. They reflect judgments regarding the model domain and the resolution needed to assess risks adequately. Some risk assessments, however, may be restricted to specific facilities, towns, time frames, and so forth. These may have true values. Uncertainty about domain parameters may also be considered a form of model uncertainty. If the domain is the XYZ processing plant, it is trivially specific and objective. The hinterland affected by economic activity at the Port of Los Angeles is a much more subjective determination. These kinds of quantities are most appropriately addressed through parametric variation and sensitivity analysis.

#### **2.3.3.7 Outcome Criteria**

Outcome criteria, such as illnesses, illnesses prevented, property damage, benefit-cost ratios, and the like, are output variables used to rank or measure the desirability or undesirability of possible decision outcomes. Their values are determined by the input quantities and the models that use them. Uncertainty in these values is evaluated by propagating uncertainty from the input variables to the output variables using one of several different methods. Generating the uncertainty about output criteria is the responsibility of the risk assessor; addressing it in decision making is the responsibility of the risk manager.

### **2.3.4 SOURCES OF UNCERTAINTY IN EMPIRICAL QUANTITIES**

Empirical quantities are the most commonly encountered uncertain quantities with true values that must be measured or estimated. When good measurement data are available, there may be little or no knowledge uncertainty about the true value of a parameter or variable. Even when there is no knowledge uncertainty, we may have natural variability to address in the risk assessment. It is useful to continue the excellent conceptual framework of Morgan and Henrion (1990) to consider the different sources of uncertainty in empirical quantities. Understanding the reasons that you are uncertain about empirical quantities is essential to your ability to choose an effective treatment of that uncertainty in a quantitative risk assessment.

#### **2.3.4.1 Random Error and Statistical Variation**

Measurements are rarely perfectly exact. Even tiny flaws in observation or reading measuring instruments can cause variations in measurement from one observation to the next. Then there is the statistical variation that results from sample bias. If we take measurements on a sample, we only have an estimate of the true value of a population parameter. Classical statistical techniques provide a wide array of methods and tools for quantifying this kind of uncertainty, including estimators, standard deviations, confidence intervals, hypothesis testing, sampling theory, and probabilistic methods.



#### 2.3.4.2 Systematic Error and Subjective Judgment

Systematic errors arise when the measurement instrument, the experiment, or the observer is biased. Imprecise calibration of instruments is one cause of this bias. If the scale is not zeroed or the datum point is off, the solution is better calibration of the instrument or data. If the observer tends to over- or underestimate values, a more objective means of measurement is needed or the observer needs to be recalibrated. The challenge to the risk assessor is to reduce systematic error to a minimum. The best solution is to avoid or correct the bias. When bias can be identified, for example, the scale added 0.1 g to each measurement, it can sometimes be corrected for, that is, by remeasuring or subtracting 0.1 g from each measurement.

#### IT FEELS LIKE AN EIGHT TO ME

Much data are collected outside a laboratory and under less than ideal conditions. Which box of produce do we open and inspect? Where in the stream does the investigator insert the meter to read dissolved oxygen? How do you estimate how far away a work boat is on the open water? How quickly can you count the deer in a running herd? Subjective judgments are notoriously suspect under uncontrolled conditions.

Just like with faulty instruments, the solution is better calibration. Ideally, before the fact, but calibration is better late than never.

The more difficult task concerns the biases that are unknown or merely suspected. Estimating the magnitude of these biases is very difficult and often requires a lot of subjective judgment. Bias in subjective human estimates of unknown quantities is a topic covered extensively in the literature; see, for example, O'Hagan et al. (2006).

#### 2.3.4.3 Linguistic Imprecision

After all these years on the planet, communication is still humankind's number one challenge. We routinely use the same words to mean different things and different words to mean the same things. This makes communication about complex matters of risk especially challenging. If we say a hazard occurs frequently or a risk is unlikely, what do these words really mean? The problems can be even more pervasive than that. Tasked with measuring the percentage of midday shade on a stream, a group of environmentalists engaged in a lengthy discussion of when midday occurs and how dark must a surface be to be considered shade.

The best and most obvious solution to this kind of ambiguity is to carefully specify all terms and relationships and to clarify all language as it is used. Using quantitative rather than qualitative terms can also help. Fuzzy set theory may be an alternative approach to resolving some of the more unavoidable imprecision of language in a more quantitative fashion.



#### **2.3.4.4 Natural Variability**

Many quantities vary over time, space, or from one individual or object in a population to another. This variability is inherent in the system that produces the population of things we measure. Frequency distributions based on samples or probability distributions for populations, if available, can be used to estimate the values of interest. Other probabilistic methods may also be used.

#### **2.3.4.5 Randomness and Unpredictability**

Inherent randomness is sometimes singled out as a form of uncertainty different from all others, in part because it is irreducible in principle. The indeterminacy of Heisenberg's uncertainty principle is one example of inherent randomness. However, a valid argument could be made that this is just another instance of knowledge uncertainty because we simply have been unable to resolve this puzzle at the present time.

This cause of uncertainty identifies those uncertainties that are not predictable in practice at the current time. Examples include such things as when the next flood will occur on a stream or where the next food-borne outbreak will occur in the United States. Such events can be treated as a legitimately random process. The danger here is the personalist view of randomness that could emerge, where randomness is a function of the risk assessor's knowledge. Phenomena that appear random to one assessor may be the result of a process well known by a subject matter expert. Strong interdisciplinary risk assessment teams combined with peer involvement and peer review processes provide a reasonable hedge against this sort of problem arising. Uncertainty about such quantities can be addressed by a full range of methods, from narrative descriptions through probabilistic methods.

#### **2.3.4.6 Disagreement**

Organizations and experts do not always see eye to eye on matters of uncertainty. Different technical interpretations of the same data can give rise to disagreements, as can widely disparate views of the problem. This is not to mention the real possibility of conscious or unconscious motivational bias.

Disagreements can sometimes be resolved through negotiation and other issue resolution techniques. Allowing the disagreements to coexist is also an option. Sensitivity analysis would consider the results of the analysis using each different perspective. A common approach for some disagreements is to combine the judgments using subjective weights.

#### **2.3.4.7 Approximation**

There may be instances when it is useful to approximate values of one quantity with another quantity. This is sometimes done with microbial dose-response curves where values for one species are used to approximate values for another species. Uncertainty due to approximation is also similar to what we called model uncertainty, earlier in this chapter. The fact that the model is a simplified version of reality ensures that uncertainty will remain about the outcome criteria. We are only able to approximate the function of complex systems because of scenario, model, and quantity uncertainty. Methods for dealing with this source of uncertainty will depend on the specific limitations of the approximation.



## 2.4 BEING INTENTIONAL ABOUT UNCERTAINTY

Risk analysis is decision making under uncertainty. It requires risk assessors, risk managers, and risk communicators to become intentional about uncertainty. Here are 10 actions to take to become intentional about uncertainty in decision making:

1. Recognize that uncertainty exists and is relevant in your decision problem.
2. Identify the specific things that are uncertain and the sources of that uncertainty.
3. Identify the instrumental uncertainties among the uncertainty. These are the uncertainties that have the potential to affect the decision or decision outcomes.
4. Acknowledge the relevant uncertainty and make risk managers, other decision makers, and stakeholders aware of instrumental uncertainties.
5. Choose appropriate tools and techniques to address each source of instrumental uncertainty.
6. Complete the assessment and other analyses incorporating these tools and techniques.
7. Understand the results of your uncertainty analysis.
8. Identify any options for further reducing the remaining instrumental uncertainty.
9. Convey your results and the significance of the uncertainty for decision making and decision outcomes, as well as any options for reducing the residual uncertainty, to decision makers in a manner that enables them to use this information in decision making.
10. Proclaim the uncertainty and its potential impacts on decision outcomes to all appropriate stakeholders.

### ROCK IN THE CHANNEL

During one proof-of-concept, risk-based estimate of costs in the early 1990s, a design engineer was asked to estimate the percentage of rock in a channel bottom with an estimated interval. He declined to do so; when pressed, he refused. His justification was that he had much more and much better data than he normally has. He was offended by the notion that he might not know how much rock was actually in the channel bottom. His point estimate proved to be off by a significant amount. He has become a supporter of interval estimates.

The process begins by recognizing uncertainty when it exists, and it almost always exists. It is not unusual for experienced professionals to underestimate the things they do not know or to overestimate the quality of their evidence. Experts are often confident, not so much because of what they actually know as what they believe to be true. Biases, mindsets, and beliefs can prevent some people from recognizing that uncertainty exists. Experts are often correct in their intuitive judgments, and this strongly reinforces those biases. Thus, the starting point for all risk work is to begin by recognizing the existence of uncertainty. This may, at times, require analysts to challenge one another. To challenge false beliefs in certainty, ask: “What is your



evidence for your beliefs about this problem?” When experts can produce evidence, it is reassuring. When they cannot, it can be enlightening.

Once the existence of uncertainty is recognized it is necessary to specifically identify what is known with certainty and what is not. The analyst’s job is to identify those uncertain things that are most important to decision making. These would be scenarios, theories and knowledge, models or quantities that if not certain could affect decision making or decision outcomes. It is not unusual to find many potential sources of uncertainty. Some of these will be more important than others, and risk assessors and other analysts need to be able to identify uncertainties that are instrumental from those that are not. Risk managers do not need to be concerned with every potential uncertainty. In some instances, instrumental uncertainties may not be identified until after the assessment is completed.

There are going to be people who need to know about the uncertainty perhaps even before you begin to address it. Consider a large public works project, where design engineers are uncertain about the existence of seismic zones in the project footprint. This could affect the work of cost estimators and others who need to know this. Acknowledging the known uncertainties early in the assessment process is an important first step in risk communication. Partners in the decision-making process are certainly going to need to know the limitations of the available data.

Matching an appropriate tool and technique to the uncertainty is an important analytical step. Some uncertainty can be addressed in a qualitative risk assessment. Other uncertainty may require a probabilistic risk assessment. Between and beyond these approaches lie many tools and techniques, some of which are described in [Chapter 10](#).

Characterizing the risks and the uncertainty that is associated with them for a decision problem requires analysts to pull together the many and disparate approaches for addressing uncertainty that may have been used and to complete the analyses. It is important for the analysts to spend sufficient time with the results of their analyses to understand them and the uncertainty that attends them well enough to explain its implications for decision making and decision outcomes to risk managers and other decision makers.

In best practice, analysts will be able to distinguish the effects of knowledge uncertainty from the effects of natural variability. This will enable the analyst to identify potential options for further reducing the uncertainty in the risk assessment and other analyses. One of the greatest challenges, and an area of risk analysis that has not yet received sufficient attention, is to convey the results, the significance of the uncertainty, and any options for reducing uncertainty to decision makers. This is the subject of [Chapter 19](#) on decision making under uncertainty.

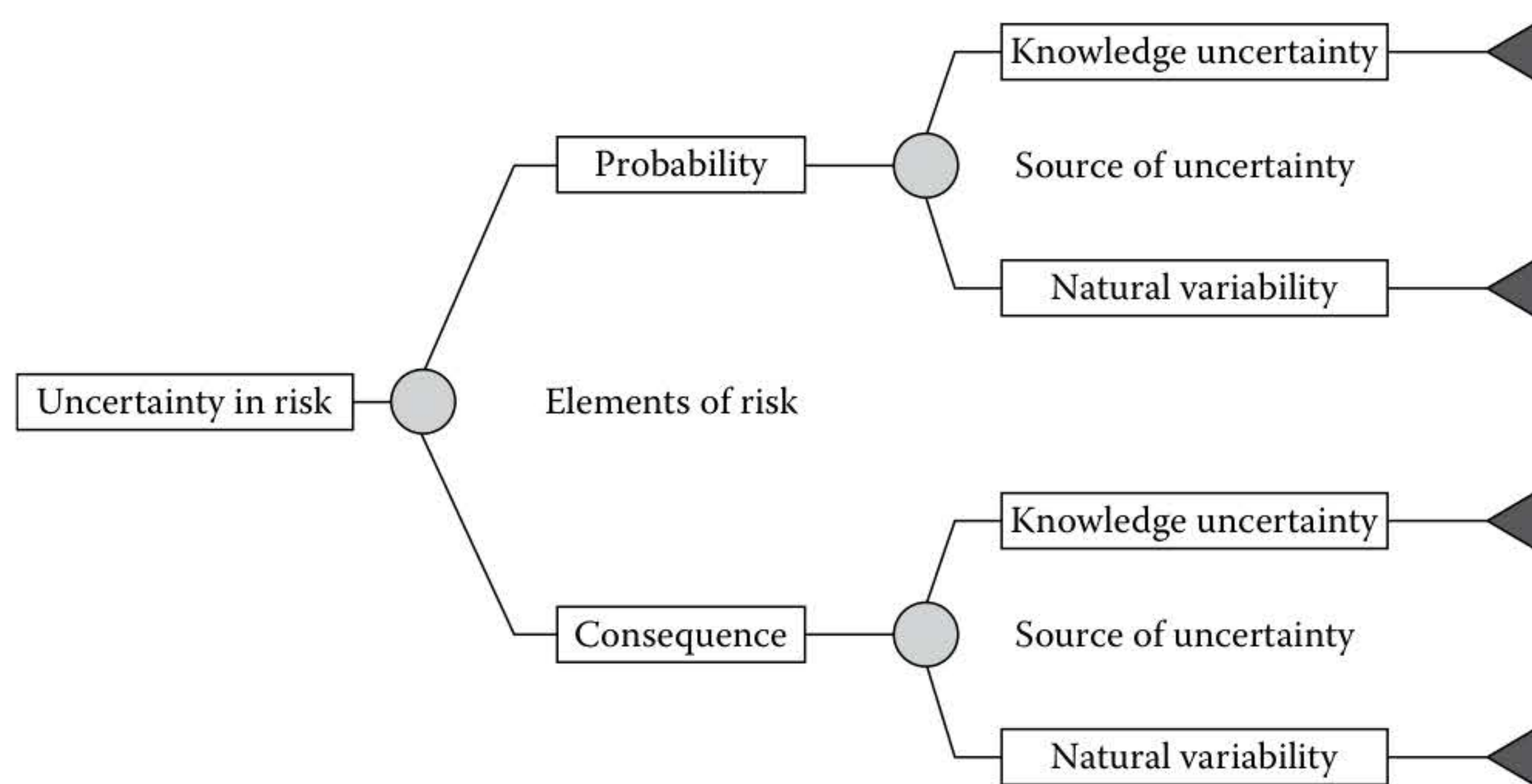
It is the risk assessor’s responsibility to identify and address the instrumental uncertainty in their decision problems. Some of the simpler tools available include narrative descriptions of the uncertainty, clarification of ambiguous language, negotiation for differences of opinion, and uncertainty or confidence ratings for these analyses. When the relevant uncertainty could lead to dramatically different futures and a few key drivers of this uncertainty can be identified, scenario planning is a useful technique. In more quantitative analyses, assessors can use parametric variation, bound uncertain values, and use sensitivity analysis or other quantitative risk assessment methods, all of which can include both deterministic and probabilistic analysis.



It is the decision maker's responsibility as risk manager to address instrumental uncertainty in decision making. In order to do that, risk assessors must make sure decision makers, in their risk management responsibility, understand the potential for instrumental uncertainty to affect decision making or the potential outcomes of any specific decision. [Chapter 19](#) provides a practical approach for risk managers to follow in addressing instrumental uncertainty in decision making. It also includes a discussion of criteria that have been developed for choosing from among alternative risk management measures under uncertainty. They include:

- Maximax criterion—choosing the option with the best upside payoff.
- Maximin criterion—choosing the option with the best downside payoff.
- Laplace criterion—choosing the option based on expected value payoff.
- Hurwicz criterion—choosing an option based on a composite score derived from preference weights assigned to selected values (e.g., the maximum and minimum).
- Regret (minimax) criterion—choosing the option that minimizes the maximum regret associated with each option.

Once a decision is made the potential impacts of uncertainty on the decision's outcomes must be vigorously proclaimed to all stakeholders with a legitimate interest in knowing how they may be affected by the decision and the uncertainty that attends it. Making this effort to be honest brokers of information, saying what we do and do not know, and stating the significance of the latter for decision making distinguishes risk analysis from other decision-support frameworks and tools. As [Figure 2.3](#) shows, the uncertainty encountered in an assessment of a risk can be found in either its probability or consequence. It can be due to knowledge uncertainty or natural variability. It is the risk assessor's responsibility to address significant relevant uncertainties in their assessments. Risk managers are expected to address instrumental uncertainty in their decision making.



**FIGURE 2.3** Source elements of uncertainty in risk analysis.



## 2.5 SUMMARY AND LOOK FORWARD

Uncertainty is the reason for risk analysis. Risk analysis is, in a sense, the confluence of social values and science. Uncertainty at the macro level affects values through a constantly and rapidly changing social environment. Uncertainty at the micro level occurs in the specific details of the problems decision makers face, at the level of our scientific knowledge. The two levels of uncertainty can pose markedly different challenges to risk analysts.

Separating what we know from what we do not know is a primary responsibility of the risk assessor. In the “pile” of things we do not know about a given decision problem are things that reflect our knowledge uncertainty and things that are naturally variable. It is important to know the difference between the two. Knowledge uncertainty is, in principle, reducible, while natural variability is not. This can be important to how risks are assessed, managed, and communicated.

A major purpose of risk analysis is to push risk assessors and risk managers to be intentional in how they address uncertainty in assessment and decision making. There are helpful taxonomies to aid our thinking about how to identify uncertainties and their causes. These are important to know because different kinds and causes of uncertainty have different sets of appropriate treatments. It is the risk assessor’s job to address knowledge uncertainty and natural variability in risk assessment inputs. It is the risk manager’s job to address them in risk assessment outputs.

The next three chapters will carefully unpack and explain the basic activities that comprise the three components of the risk analysis model presented in [Chapter 1](#). We begin with the risk management process, which is the cornerstone of the risk analysis process. Although there are many well-developed risk management models already in use, the approach taken here is not to put any one of these before the others so much as to find the common ground in all of them to aid your understanding and practice of the risk management process.

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# 3 Risk Management

## 3.1 INTRODUCTION

In the past, many organizations have managed risks by prescribing standards, policy, procedures, regulations, and other guidance, the rationale being that if you follow the “rules,” then the ensuing results must be okay. That is not risk management. Risk management, done well, is intentional about its process, addresses uncertainty in decision making, and focuses on outcomes. Risk management is maturing. There are now thousands of people who identify themselves as risk managers when only a few decades ago few outside of the insurance industry used this title.

There is no shortage of risk management models. As with every other aspect of risk analysis, many disciplines and organizations have spawned their own particular view of how to do risk management. Describing the risk management process in a generic fashion is, therefore, a daunting challenge. It is impossible to define risk management in a way that will satisfy many, much less all people. The Society for Risk Analysis defines it benignly as: “Activities to handle risk such as prevention, mitigation, adaptation or sharing.” It is not a lack of definitions that makes defining the term difficult so much as it is the proliferation of definitions in use by organizations and found in the literature. The U.S. Environmental Protection Agency’s *Thesaurus of Terms Used in Microbial Risk Assessment*, for example, identifies 12 different definitions for risk management (EPA, 2010).

It goes without saying that most organizations are quite fond of the nuances or parsimony of their own definitions and are not inclined to surrender it for another. No one seems to be clamoring for a universal definition, so do not look for one here. In place of a formal definition, the risk management component is described in some detail. That description will not be any more universally applicable than a definition would be, but we must begin somewhere, so we begin by identifying those risk management activities that are common to many definitions, models, and practice.

### A SAMPLING OF RISK MANAGEMENT DEFINITIONS

The culture, processes, and structures that are directed toward the effective management of potential opportunities and adverse effects. (Australia/New Zealand Risk Standard)

The sum of measures instituted by people or organizations in order to reduce, control, and regulate risks. (German Advisory Council on Global Change)

Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyze, and compare regulatory and



nonregulatory options and to select and implement appropriate regulatory response to that hazard. Risk management involves three elements: risk evaluation; emission and exposure control; risk monitoring. (IPCS)

Coordinated activities to direct and control an organization with regard to risk. (ISO/IEC Risk Management Vocabulary)

All the processes involved in identifying, assessing, and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress. Good risk management helps reduce hazard and builds confidence to innovate. (UK Government Handling Risk Report)

The process of analyzing, selecting, implementing, and evaluating actions to reduce risk. (U.S. Presidential/Congressional Commission)

The process of evaluating alternative regulatory actions and selecting among them. (U.S. National Research Council “Red Book”)

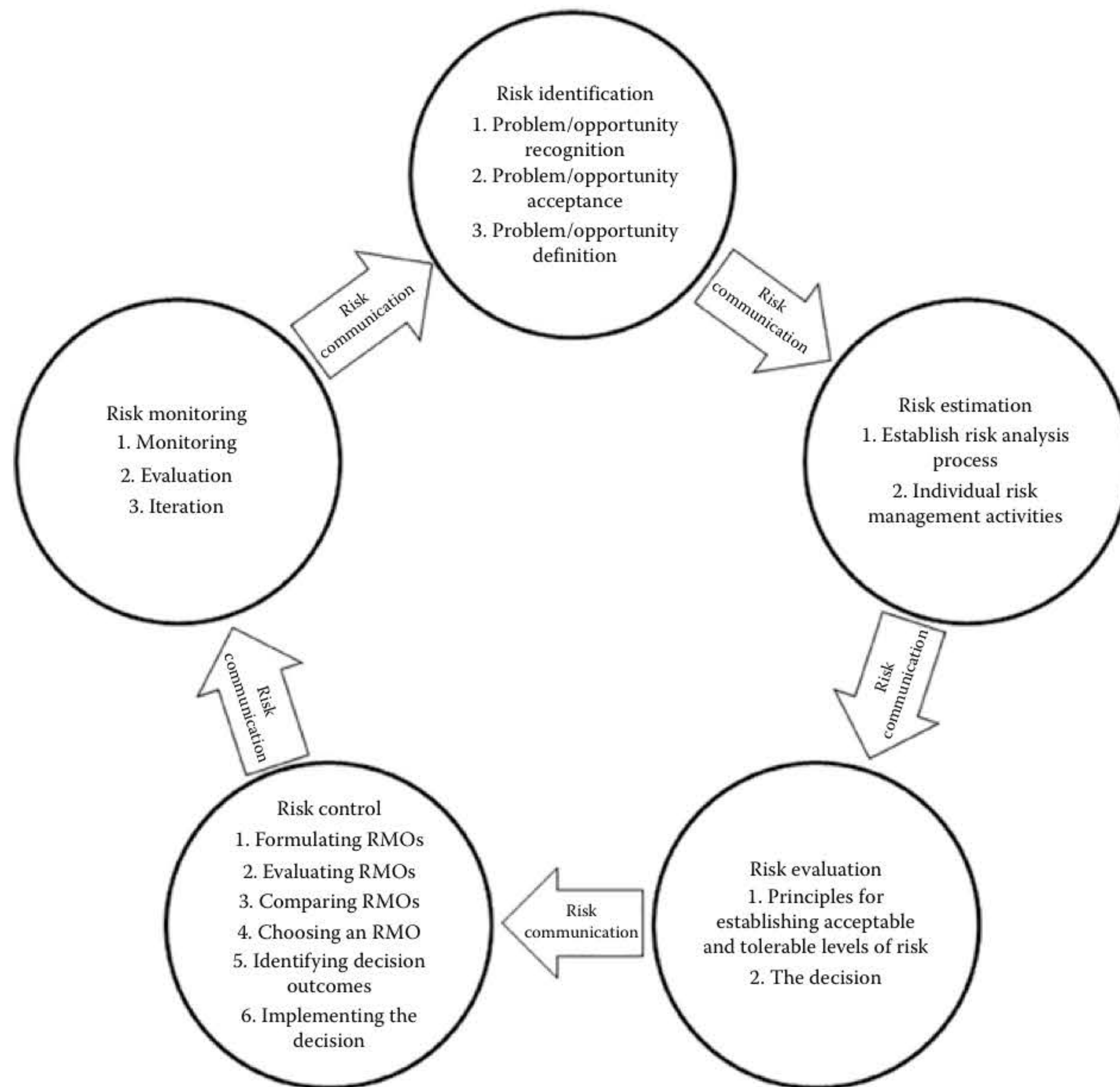
I am going to call a new initiative undertaken by an organization that practices risk analysis a risk management activity. There are five basic parts to a risk management activity, all connected by continuing risk communication. The five parts are:

1. Identifying risk
2. Estimating risk
3. Evaluating risk
4. Controlling risk
5. Monitoring risk

A generic model is shown in [Figure 3.1](#). It shows the five parts in a continuous loop in order to capture the iterative nature of risk management. Risk management is making effective and practical decisions under conditions of uncertainty. As long as there is any uncertainty, a risk management decision is conditional, that is, based on what was known and not known at the time of the decision. As the uncertainty is reduced in the future or as the outcomes of the management decision become known, it may be prudent to revise the decision; hence, the ongoing nature of risk management. Every decision is based on what we know now and is subject to further revision in the future; in that sense no decision is necessarily final as long as instrumental uncertainty remains. Expanding on and explaining the elements of the risk management model of [Figure 3.1](#) is the primary work of this chapter.

You will find this to be a wide-ranging chapter, as befits the risk manager’s job. I have distilled the most consistent elements of a great many risk management models (see e.g., Presidential/Congressional Commission, 1997; FAO, 2003; FDA, 2003; ISO, 2009), as well as my own experience, to the five broad parts of a risk management activity, which are described here in some detail. To round out the discussion, a few specific risk management models are offered at the end of the chapter to illustrate how different organizations approach the risk management task, which is basically to make effective decisions about whether and how to manage risks with less than all the information desired.





**FIGURE 3.1** A generic risk management process comprising five tasks.

### 3.2 IDENTIFYING RISKS

Something happens to start a risk management activity. That something is usually a problem that needs attention or an opportunity\* that can be pursued. In [Chapter 1](#), a risk identification process consisting of the following steps was identified:

- Identify the trigger event.
- Identify the hazard or opportunity for uncertain gain.
- Identify the specific harm or harms that could result from the hazard or opportunity for uncertain gain.
- Specify the sequence of events that is necessary for the hazard or opportunity for uncertain gain to result in the identified harm(s).
- Identify the most significant uncertainties in the preceding steps.

In this expanded discussion it will be convenient to think of risks a little differently, as problems and opportunities.

\* To avoid the awkward redundancy of saying problem/opportunity throughout this section, let it be understood that problem will stand for both kinds of risky situations.



Einstein is reported to have said, “If I had one hour to save the world, I would spend 55 minutes defining the problem.” This is the stake that good risk analysis drives into the ground at its outset that helps distinguish it from other decision-making paradigms. The purpose of risk analysis is to find the right problem and to solve it. Identifying the problem (see [Figure 3.2](#)) provides a focal point for all of the risk manager’s subsequent decision-making efforts.

What often happens in organizations is that as soon as a problem arises we are so eager to solve it that we spend very little time understanding, refining, and communicating our understanding of it. As a consequence, organizations often treat the symptoms of problems rather than their causes. Worse, we often do not even know when we are unclear about a problem, and frequently the result is that we solve the “wrong” problem correctly.

### EXAMPLES OF TRIGGERS FOR RISK MANAGEMENT ACTIVITIES

*Crisis:* Real or perceived, media, public outcry, adverse comments, changing public values or awareness, decreased consumer confidence, other

*Science and technology:* New knowledge or technology, emerging health problem, improved detection, surveillance, or method

*Emerging or “on the horizon”:* Planned search, forecasting, scan risk landscape, natural and anthropogenic disasters and events, imports

*Strategic plan:* Strategic planning, social needs, opportunities, can be beyond the horizon, historical precedents

These examples of the kinds of events and inputs that can trigger a risk management activity are from the US Food and Drug Administration (FDA) *Center for Food Safety and Applied Nutrition Risk Management Framework* (FDA, 2003).

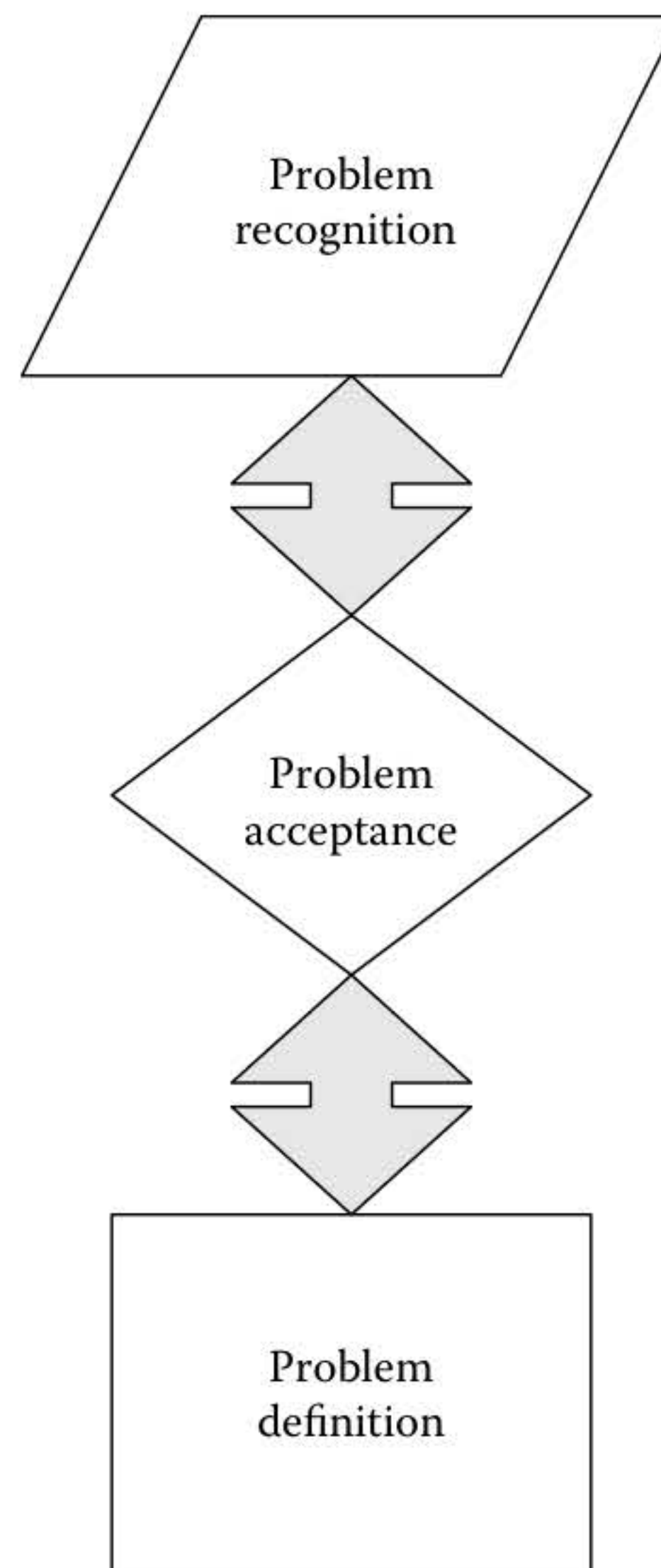
Problem identification, the risk manager’s first major responsibility, is defined here as a three-part process (see [Figure 3.2](#)).

- Problem recognition
- Problem acceptance
- Problem definition

#### 3.2.1 PROBLEM RECOGNITION

Problem recognition is the simple act of recognizing that a problem exists and gaining an initial understanding of the problem. This happens in one of two broad ways. Reactive or passive problem recognition is when a problem finds you. These are problems triggered by outside influences. Stakeholders bring you a problem or an event occurs that results in a problem you cannot ignore. Alternatively, there is





**FIGURE 3.2** Problem identification steps.

proactive or intentional problem finding, in which management looks actively and often strategically for the most important problem(s) to solve.

Despite the seemingly obvious nature of this task, it is surprising how frequently organizations fail to recognize a problem. This is all the truer in a risk analysis context because risky problems often lurk unseen over the horizon or around the corner. They are frequently hidden from view, obscured by uncertainty and higher priorities, and occluded by smoke from the organizational brushfires that need constant tamping out. Anyone can recognize the problem that forces its way through your door and onto your desk at 4 p.m. on a Friday afternoon. It takes a risk manager to see the problems just over the horizon or just around the corner.

Recognizing the existence of opportunities for potential gain or betterment parallels the process of problem recognition. Fewer opportunities seem to break down the risk manager's door than do problems, however, and the search for opportunities is usually more active.

### 3.2.2 PROBLEM ACCEPTANCE

Once a problem makes your radar screen, the question becomes, "Will you own it and do something about it?" The second step in problem identification, therefore, is problem acceptance. This requires risk managers to articulate the problem they have



found in enough detail to determine if it is a problem they are willing and able to address. Addressing a problem means allocating resources to its solution.

Risk managers must identify the resources required to address the problem in a timely manner. Then they must evaluate the adequacy of their available resources in the context of their program authorities, organizational mission, and vision. This obviously implies consideration of competing uses for the organization's resources. We cannot solve every problem.

Problem acceptance is a priority-setting step. It is deciding to act. Accepting a problem as one to be solved or an opportunity as one to be pursued is a significant organizational commitment. Our understanding of the problem is revised and refined beyond the initial recognition in this step. Risk managers must identify and commit to the time frame and resources required to address each problem they accept.

Choosing from a number of potential opportunities and deciding which are worth pursuing is a common challenge in business decision making. Articulating and accepting the opportunities to be pursued parallels the problem acceptance step.

### 3.2.3 PROBLEM DEFINITION

The third step is problem definition. This is when the problem is fully articulated for the first time and linked to possible solutions. Opportunities are likewise articulated and linked to potential strategies that could realize the gains. Information needs begin to become clear and a risk management activity is initiated. This step encompasses a focused and intentional effort to provide a commonly understood description of the problem. It includes stakeholder input when appropriate.

If you cannot clearly and concisely finish the sentence, "The problem is ...," then nothing that follows will be clear either. A written "problems and opportunities statement" is the desired output of this problem identification process. Your problems and opportunities statement provides the rationale or reason for your risk management activity. It should be considered a conditional statement that will change as you begin to gather information, reduce the initial uncertainty, and better understand the problem(s) and stakeholders' concerns. So, date that piece of paper. Risk analysis is an iterative process and you can expect to revise and refine your problems and opportunities statement several times before you are done.

#### **SAMPLE PROBLEMS AND OPPORTUNITIES STATEMENT**

- P1: Increasing resistance of *Campylobacter* in chicken to fluoroquinolones due to subtherapeutic use of antibiotic drugs in food producing animals.
- P2: Declining efficacy in the use of fluoroquinolones for the treatment of fluoroquinolone-resistant campylobacteriosis in humans.
- O1: Reduce incidence of all campylobacteriosis in humans due to consumption of chicken.

The stakeholders in any problem context will vary. For some problems the stakeholders may comprise the general public and many special interests. In other



problem settings the stakeholders may be wholly contained within the risk managing organization. Stakeholders, however defined, should be involved in the problem identification process. The appropriate level of involvement will vary with the decision problem and its context. Some problems will be identified for you by stakeholders; at other times they will have to be made aware of the existence of a problem.

Vet your problems and opportunities statement with your stakeholders. Publish it appropriately. Make it public if your stakeholders include members of the public. Show them your best thinking and ask, “Did we get the problem(s) right? What is missing? What is here that should not be? Do you have information about these problems and opportunities that would be helpful to share?” Stakeholders can be an effective ally in reducing uncertainty.

The output of this activity is a revised problems and opportunities statement. Keep that statement up to date. Let people know how it changes and why it changes as it changes.

### 3.2.4 FROM PROBLEMS AND OPPORTUNITIES TO RISKS

Given a problems and opportunities statement, it is straightforward to identify the risks to be addressed in a decision. Very often the statement itself will suffice as a summary identification of risks. However, for clarity, it would be wise to expand each problem and opportunity using the risk identification steps presented at the outset of this section, described in detail in Section 1.2.

## 3.3 RISK ESTIMATION

Estimating risks is the assessor’s job. It cannot be done without direction and guidance from the risk manager. Risk managers have an important, but limited, role in the science-based risk assessment process. The risk manager’s positive decision-making role is found in the risk estimation activities (see [Figure 3.3](#)) that help describe the world as it actually is. That role includes establishing the organization’s risk analysis process and managing individual risk management activities.

Recommendation 1 from the U.S. National Research Council (NRC) publication *Risk Assessment in the Federal Government: Managing the Process*, also known as the “Red Book,” has been often misunderstood to mean that the assessment and management tasks must be functionally separated and should not interact. The actual recommendation follows:

Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies

**NRC, 1983**

That is a far cry from the severe separation that has been practiced at times.



There are two groups of activities in the risk estimation part of risk management, as seen in [Figure 3.3](#). The first, developing a risk analysis process, consists of one-time or periodic activities required to establish and maintain the risk analysis process. The other, individual risk management activities, consists of duties that recur in every risk management activity. These activities are addressed in the following sections at the level of detail shown in the figure.

### 3.3.1 ESTABLISH A RISK ANALYSIS PROCESS

If the plethora of definitions for the basic terminology of risk analysis teaches us nothing else, it teaches us this: there is no one best way to do risk analysis. The most commonsense rule seems to be to use what works best for you. Think of risk analysis as a process that is firm in its principles but flexible in the details of how they are pursued.

The risk manager's job, with respect to establishing a risk analysis process, is basically to say, "This is how we do risk analysis here." This process establishes the risk management model the organization will use so that there is an agreed-upon framework for addressing risk problems and opportunities. It establishes the roles and responsibilities of everyone involved in the risk analysis process.

A significant piece of any risk analysis process is the risk assessment policy, which addresses the manner in which the many subjective judgments and choices that arise in the course of a risk assessment will be resolved to protect the integrity of the science and the decision-making process. Some predictable issues that will arise include how to deal with uncertainty and what assumptions to use when the available data are inconsistent. These are sometimes called "science policy" issues. It is wise to devise a means of identifying and resolving these kinds of problems before they are encountered in practice.

Establishing a risk assessment policy is the risk manager's responsibility. It needs to be a collaborative process for any organization that is engaged in making public policy or in the stewardship of public resources like public health, public safety, natural resources, or the environment. This collaboration should include risk managers, risk assessors, and risk communicators. It should provide appropriate opportunities for input and feedback from relevant stakeholders. The risk assessment policy should be documented and made publicly available to ensure consistency, clarity, and transparency. For most organizations outside the public sector, establishing a risk assessment policy is an internal affair.

#### SCIENCE POLICY

Science-policy choices are distinct from the policy choices associated with ultimate decision making ... The science-policy choices that regulatory agencies make in carrying out risk assessments have considerable influence on the results

NRC, 1983

When the science is unclear, what assumptions are to be made and by whom? A good risk assessment policy addresses these questions and all questions of "so-called" default assumptions.



One of the hallmarks of best-practice risk analysis is insulating the science from the policy. In the early days of risk analysis, many thought the risk management and risk assessment tasks must be totally separated from one another. This is not true. It is best when these functions are separate and handled by different people with the appropriate skill sets required by their jobs. However, it is absolutely essential that managers and assessors communicate, cooperate, and even, at times, collaborate throughout the risk analysis process.

### **A SCALABLE PROCESS**

A good risk management process is perfectly scalable. You can use it when you have 30 minutes and no budget as easily as you can over years with millions of dollars.

Its greatest value is that it provides a systematic, science-based approach to solving problems and managing risks.

Risk managers begin and end the risk assessment process. They may collaborate with risk assessors in identifying a problem, in formulating risk management options, or on other tasks throughout the risk management activity. They will cooperate in the conduct of the risk assessment and must communicate continuously throughout the iterative risk analysis process.

The output of this task is a well-defined risk analysis process that will guide the organization. That process should include a specific risk management model and a risk assessment policy. Both of these should be carefully documented and publicized to all those with a legitimate interest in the organization's risk analysis process.

### **3.3.2 INDIVIDUAL RISK MANAGEMENT ACTIVITIES**

Risk managers have several specific preliminary risk management responsibilities to complete before, during, and after the risk assessment. Identifying the right problem to solve is only the starting point. Additional responsibilities include:

1. Develop a risk profile
2. Establish risk management objectives
3. Decide if a risk assessment is needed
4. Request needed information
5. Initiate the risk assessment
6. Coordinate the conduct of the assessment
7. Consider the results of the assessment

Each of these activities is considered in turn in the following sections.

#### **3.3.2.1 Develop a Risk Profile**

Risk profile is a term with two distinctly different meanings. In its current context it is an initial data gathering effort. In an enterprise risk management (ERM) context,



a risk profile is something between a description of a set of risks of concern to an organization (and, thus, not markedly different from this current context) and a high-level assessment of the types of risks an organization faces. Be aware, this is a potentially confusing term. The ERM context of the term is revisited at length in [Chapter 6](#).

Once the problems have been articulated in a problems and opportunities statement, it is time to quickly find out what is and is not known about the decision problem. A risk profile presents an analysis of the types of risks an organization, asset, project, or individual faces based on available information. In the current context, a risk profile frames problems and opportunities in their risk context and provides as much information as possible to guide subsequent risk assessment, risk management, and risk communication activities. It also provides the first formal identification of the uncertainty in your decision problem.

#### **INFORMATION YOU MIGHT FIND IN A RISK PROFILE**

- Latest statement of the problem
- Description of the hazard or opportunity involved
- How assets are exposed to the hazard
- Frequency, distribution, and levels of occurrence of the hazard
- Identification of possible risks from the available scientific literature
- Nature of values at risk (human health, economic, cultural, etc.)
- Distribution of the risk and benefits from the risky activity
- High level or preliminary assessment or prioritization of the risks
- Characteristics of available risk management options
- Current risk management practices relevant to the issue
- Public perceptions of the potential risks
- Information about possible risk management (control) measures
- Preliminary identification of important scientific data gaps that may prevent or limit a risk assessment
- International implications of risk management
- Risk management objectives
- Decision to pursue a risk assessment
- Questions to be answered by risk assessment

The risk profile is the risk manager's responsibility. Managers need not do it alone or at all, for that matter, but they need to see that it is done. Profiling a risk will almost surely mean consulting and collaborating with risk assessors, and it may involve stakeholders. The preliminary risk identification is fleshed out and expanded upon in the profile. Think of this as the point at which the risk management activity team provides a situation report based on available evidence and information that more carefully develops our understanding of what can go wrong, how it can happen, the consequences of it happening, and how likely it is to happen. The profile presents the current state of knowledge related to the risks identified in a concise form at the



outset of the risk management activity. The profile will also include consideration of potential risk management options identified to date.

The profile step is important for several reasons beyond the fact that it identifies data gaps by separating what we initially know about a problem or opportunity from what we do not know. It develops the risk analysis team's knowledge and understanding of the problem and may evolve the risk identification further. It also provides the basis for some very important preliminary risk management tasks, including:

- Identifying risk management objectives
- Deciding whether or not to initiate a risk assessment
- Identifying the questions to be answered by risk assessment.

One of the most important functions of the risk profile is to reduce and better define the uncertainty relevant to the decision problem. When a risk is initially identified, it is likely that the uncertainty is going to be great. As the first formal information-gathering step in the process, the risk profile is often effective in reducing uncertainty and identifying the greatest remaining data gaps. A risk profile sometimes provides enough information to make a risk management decision.

The term *risk profile* is used extensively by the food safety risk analysis community, for one example. It may be an unfamiliar term to other communities of practice. However, the initial data-gathering step is or should be universal in any risk management activity. Finding out what is already known or readily knowable about the identified risks precedes the risk assessment. In fact, it is an essential step in deciding whether a risk assessment is even needed or in some instances whether it is doable.

The output of this step is a documented risk profile that includes the initial sorting and assessing of the things that are not known about the identified problems and opportunities. Documentation may be in a brief report, an organized sheaf of papers, an electronic folder of information sources and memoranda, or an oral narrative. A formal document is not always required.

### 3.3.2.2 Establish Risk Management Objectives

Objectives say what we desire to see happen and when. They define what success looks like. An objective is a clear statement of a desired outcome of the risk management activity. It is easy to confuse objectives with strategies, which describe how we intend to achieve the objectives. It is the risk manager's job to write the risk management objectives. They should be specific and conceptually measurable.

#### SAMPLE OBJECTIVE WORDS

Eliminate, reduce, minimize/maximize, enhance, harmonize, identify, define, describe, increase/decrease, raise/lower, strengthen/weaken, avoid, adapt, blend, reconcile, coordinate, affirm, diminish, weaken, promote, raise, complement, strengthen.



Once the risk has been profiled and the decision context is better understood, risk managers need to determine their broad risk management objectives. The problems and opportunities statement describes why a risk management activity has been initiated. The objectives state in broad and general terms what the risk managers intend to do about the problems and opportunities they face. These objectives should reflect the most important social (or organizational) values in the decision process.

### **A GOOD OBJECTIVE IS**

*Specific:* It is clear and free from ambiguity

*Flexible:* It can be adapted to new or changing requirements

*Measurable:* Its achievement can be documented by some objective means

*Attainable:* It can be reached at the end of a course of action

*Congruent:* It is in harmony with other objectives

*Acceptable:* It is welcome or pleasing to key stakeholders

Objectives do not identify specific risk management options, they are not solutions to the problem(s) identified. They identify the intended purposes of the risk management activity. An objective is a clear statement of a desired end that risk management options are intended to accomplish.

Where do these objectives come from? Values! They reflect what is important to people. You can find values in what concerns the public, the experts, and our institutions (law, regulations, guidance, policy, organizational missions).

### **A GOOD OBJECTIVE IS NOT A**

*Management option:* It does not prescribe a specific course of action

*Government goal:* It is not a political or governmental objective

*Risk assessment task:* Developing a dose-response curve is not an objective

*Resource constraint:* It does not address time, money, or expertise

*Absolute target:* It does not specify a particular level of achievement

Consider a risk management objective related to a health risk. The objective may be to reduce or eliminate the health risk. An objective does not say how that can or should be done, only that it is an objective to do so. Objectives related to economic values might include increasing jobs, income, and profits or minimizing costs. Objectives related to other public values might include things like protecting children or the environment.

Objectives reflect the most important social (or organizational) values in the decision-making process. They identify the things risk managers are trying to do. Sometimes there are important things we are trying not to do. These things we will



call constraints. Examples of constraints include not creating new risks, avoiding the loss of jobs or income, and avoiding negative impacts on endangered and threatened species. Constraints, as used here, should not be confused with resource or schedule limitations.

A formal and written objectives and constraints statement is the desired output of this task. Consider it conditional and subject to change as uncertainty is reduced and you iterate your way through the risk management activity.

This is one of the critical ways in which social values are appropriately reflected in the risk analysis process. Stakeholder input is essential for identifying good objectives and constraints. Like the problems and opportunities statement, this statement should be published and vetted as appropriate to the decision problem's context. Seek input to the formation of these objectives and ask for feedback on your statement. Not every risk management activity is going to require the same kind of review process. Private organizations making internal decisions may require no public involvement, while some government organizations may require extensive public involvement.

#### **SAMPLE OBJECTIVES AND CONSTRAINTS STATEMENT**

- O1: Reduce *Campylobacter* antimicrobial resistance to fluoroquinolones.
- O2: Reduce the number of cases of human illness due to resistant *Campylobacter* in chicken.
- O3: Support the economic viability of chicken production.
- O4: Improve animal welfare in chicken production.
- C1: Do not increase the number of nonfluoroquinolone resistant cases of *Campylobacteriosis*.

The success of a risk management activity is defined by the extent to which objectives are met and constraints are avoided. That makes preparing this statement one of the most critical steps in the risk management process. These are the things we must do and must avoid doing to succeed in solving the problems and attaining the opportunities we have identified. If we do not meet our objectives to at least some extent, our risk management activity has failed. If we violate our constraints, our risk management activity has failed.

The chain of logic is simple in best-practice risk management. If you meet your objectives and avoid your constraints, you will have solved your problems and attained your opportunities. Objectives and constraints provide a sound foundation for formulating and, later, evaluating risk management options.

So far, we are describing a rather broad and open risk management process. Not every risk management activity will require such breadth and openness. Some risk management activities are laser-focused on recurring issues of interest to only a few people. The process we are describing works as well for these activities as it does for public policy making. Risk management is a perfectly scalable process. Objectives, for an example, can be identified in 5 minutes, 5 hours, or 5 days.



### 3.3.2.3 Decide the Need for a Risk Assessment

Your risk profile is complete, do you need a risk assessment? Not every risk management activity requires a risk assessment. Every risk management activity requires science-based evidence, but there will be times when there is enough evidence and knowledge in a room full of experts to know how to solve a well-defined problem. Other times the risk profile will produce sufficient information to enable risk managers to know how to solve their problems and realize their opportunities.

When an issue requires immediate action or when a risk is well described by definitive data, a risk assessment will not be needed. If the risk managers already know what decision they are going to make, a sham assessment is not needed to justify a foregone decision. A relatively simple problem with little uncertainty, where the consequences of a wrong decision are minor, does not require a risk assessment. When the cars are speeding by, stay on the sidewalk. If the milk has turned sour, throw it away. Do not build in the floodplain. There are many instances where there is no need for a risk assessment. Then there will be times when the risk profile is insufficient for decision making.

#### WHAT'S IN A RISK ASSESSMENT?

Want to start an argument? Go to a conference or listserv of risk people and ask the above question.

Risk assessment, like everything else about risk analysis, has many different definitions. A significant point of division for many seems to be whether risk assessment includes analysis that enables risk managers to evaluate the risks in addition to the analysis required to assess the risk. This could include, for example, benefit-cost analysis of risk management options. Some insist that such information is not and should not be part of risk assessment. They consider this risk management information that is used to evaluate the acceptability of an assessed risk or risk management option.

This narrow view may work for certain kinds of risk, like public health risks. But it falls apart for other kinds of risk, like risks of financial or economic losses and gains.

For our purposes, it is not so important where the necessary decision-making information is included as that it is included. So be aware that in some interpretations risk assessment includes information from the natural sciences only, while in others it may include much more extensive information.

A risk assessment can be useful when the data are not complete and there is much uncertainty or when there are multiple values in potential conflict. Risk assessments clarify the facts and are useful for issues of great concern to risk managers or stakeholders or when continuous decision making is in order. Risk assessment is sometimes used to guide research by identifying data gaps and significant uncertainties that need to be reduced. Assessments can establish a baseline estimate of a risk or examine the potential efficacy of new risk management options. They may be helpful



in resolving international disputes. Practical issues that can affect the decision to do a risk assessment include:

- The time and resources available
- The urgency of a risk management response
- Consistency with responses to other similar issues
- The availability of scientific information

Deciding to do a risk assessment is a distinct result of the risk profiling task. A risk assessment should be requested when two conditions are met:

1. The risk profile fails to provide sufficient information for decision making.
2. The risk profile suggests there is sufficient information to complete a risk assessment.

Sometimes there is so much uncertainty and such sparse data that it is not even feasible to attempt a risk assessment. In these situations, risk managers may make a preemptive decision based on caution or some other set of values. Alternatively, the risk profile results can be used to direct research toward filling the most critical data gaps so that risk assessment can then proceed. The decision of whether or not to do a risk assessment is often based on the results of the risk profile. That decision is the desired output of this activity. The remainder of this risk estimation discussion assumes that a risk assessment will be completed.

#### **REASONS FOR A RISK ASSESSMENT**

- The information you have is not the information you want
- The information you want is not the information you need
- The information you need is not the information you can obtain
- The information you can obtain costs more than you want to pay

*Source:* Adapted from Bernstein (1996).

#### **3.3.2.4 Request Information Needed**

If the risk profile does not provide enough information to decide how to solve the problems or pursue the opportunities, risk managers must ask for the information they need to do so. They are going to need specific kinds of information in order to be able to meet their objectives and avoid their constraints, thereby solving the problems and attaining the opportunities. No one is better positioned to know what this information is than the person who will make those decisions, the risk manager.

Some of the information risk managers will need is likely to be scientific, evidence-based, factual information. This will be provided through risk assessment and possibly other evaluations like benefit-cost analysis and legal opinions. Some of the information they need will be more subjective in nature, for example, who is



concerned with this issue and how do they feel about it? This will be obtained through other means, including a good public involvement or risk communication program.

It is absolutely essential, however, that risk managers explicitly ask for the information they know they are going to need to make a decision. It is not sufficient to issue a general request for a risk assessment based on a specific problem. Risk managers must ask risk assessors to answer specific questions in the risk assessment. If the managers do not ask the right question(s), they may not get the right information back from the risk assessment. Risk assessments that are not guided by questions to answer may produce information managers do not want to have, or they may fail to produce the information managers need to make a good decision.

### MY EXPERIENCE

I have worked on many risk management activities and risk assessments and am often called in as a consultant, usually not because things have been going well. When it is my turn to speak I hand out  $3 \times 5$  index cards and ask everyone present to write down the question(s) they believe they are trying to answer through their risk assessment.

I then collect the cards and read them aloud. Amazingly, I have yet to have two cards identify the same question(s). How do we know what data to collect, what models to build, what analysis to do when we do not even agree on what question(s) we are trying to answer?

Getting the question(s) right is the next most critical step after problem identification.

The importance of the risk manager's questions can hardly be overstated. They guide the risk assessment and other evaluations required to provide the information necessary for decision making. Once these questions are answered, risk managers have the information they need to make decisions. These questions need to come from risk managers, often with input from assessors and stakeholders.

Risk analysis supports decision making by using science and evidence to identify what we know and what we do not know. It integrates this knowledge and uncertainty with social values to meet objectives and avoid constraints and thereby to solve problems. When the initial risk profile is completed, it is time to ask the most basic of all questions: "What do we know and what do we need to know?"

Risk managers ask questions. Risk assessors answer the risk questions. Other evaluations may answer other questions. If risk managers do not ask the right questions, the analysis that follows may well not meet decision makers' needs. These questions must be available at the start of a risk assessment. They must be specific and they should be specified or at least agreed by risk managers.

It is essential that they are written down. They are not real and concrete until one can articulate them in precise words on paper. The questions will almost surely be refined by negotiation among managers, assessors, and possibly stakeholders. The questions will evolve and change as our understanding of the problem and the decisions to be made will evolve. Consequently, the questions must always be



kept up to date and they must be known to everyone who is working on the risk assessment.

The desired output of this task is a written set of questions to be answered by the assessors and other analysts of the risk analysis team. Many risk assessment problems begin with missing, incomplete, inappropriate, or just plain bad questions. To make sure they get the information they need to make a decision, risk managers need to ask for it directly.

### **SAMPLE QUESTIONS**

How many annual cases of fluoroquinolone resistant *Campylobacteriosis* currently occur in the United States due to eating chicken?

How many annual cases of fluoroquinolone resistant *Campylobacteriosis* will occur in the United States in the future due to eating chicken if there are no changes in the current usage of fluoroquinolone drugs?

How many annual cases of fluoroquinolone resistant *Campylobacteriosis* will occur in the United States in the future due to eating chicken if the use of fluoroquinolone drugs in all food producing animals is prohibited?

How many annual cases of fluoroquinolone resistant *Campylobacteriosis* will occur in the United States in the future due to eating chicken if fluoroquinolone treated chicken is sent for use in processed chicken products?

An organization with a well-defined mission and recurring issues is likely to develop standard information needs for recurring problems. When those recurring information needs become general knowledge or a standard operating procedure (SOP) this task may be simpler for everyone because they know what to do and how to do it once the information needs are institutionalized. However, every organization faces enough unique situations that this task of getting the questions right should never be overlooked.

It is impossible to anticipate all the kinds of information risk managers may require for decision making early in the process. In general, four broad categories of questions can be anticipated. Risk managers will usually want to ask questions about how to:

1. Meet objectives and constraints
2. Characterize the risks of interest
3. Mitigate the risk
4. Address other values

Risk managers may require additional information in order to know how best to meet their objectives and avoid violating their constraints. How will you achieve/avoid them? How will you measure success toward them? What kinds of information do you need to have about them in order to achieve your objectives and avoid your constraints? Some questions can be expected to focus on these kinds of concerns. They can also overlap the other question categories.



Risk characterization questions are trickier to discuss at this point because the risk assessment steps have not yet been introduced, and this is one of them. For now, think of this as the step in the risk assessment where all the various bits of information are pulled together to characterize the likelihood and consequences of the various risks you are assessing. Risk managers must direct assessors to characterize risks in ways that are going to be of most use for decision making.

Suppose a risk to public health is caused by disease and the objective is to reduce the adverse human health effects of this disease. How should assessors characterize the risks? Do managers want to know the probability of contracting this disease for a given exposure? Is the exposure of interest an annual one or a lifetime one? Might it be more useful to have the numbers of people affected by the disease? If so, are managers interested in the numbers of infections, illnesses, hospitalizations, or deaths? Are there any special subpopulations of interest to managers? Risk managers need to take great pains to ask questions at the characterization level that, when answered, will give them the information they need to make a decision about whether and how to manage that risk.

It is wise to think of risk holistically when posing risk characterization questions. There may be separate questions about existing and future risks, residual risk, transferred risk, and transformed risk. A residual risk is the risk that remains after a risk management option is implemented. When a risk management option reduces risk at one point in time or space for one kind of event or activity while increasing risk at another time or space for the same event or activity, this is called a “transferred risk.” When a risk management option alters the nature of a hazard, a population’s exposure to that hazard, or the consequences of an exposure, this is called a “transformed risk.” These concepts are not as readily applied to risks of uncertain potential gain.

Risk mitigation questions are another category of questions that will usually be appropriate to ask. What does a risk manager need to know to formulate and choose the best risk management option? What are others doing to manage this risk? What else can be done to manage this risk? How well are the different options likely to work? For example, how many illnesses will we have if there is a vaccination program? Specific questions about the efficacy of risk management options are important to ask.

Finally, there are, for lack of a better term, values questions. These focus on obvious values of importance that are not included in the objectives and constraints. Someone will almost always care about costs, benefits, environmental impacts, authority, legal considerations, and the like. Values questions may also include stakeholders’ concerns and their perceptions.

Once the questions are prepared, assessors and managers need to discuss them and what they mean. When a risk manager asks, “What is the risk of getting ill by eating an egg?” you may need to parse the question. What is meant by an egg? What kind of egg? Must it be in a shell or can it be processed? What do you mean by ill? How ill and for how long? A question that is perfectly clear to one person may be a complete mystery to another. Communication between managers and assessors is necessary to gain a clear common understanding of the questions. It may be necessary to negotiate the list of questions at times. Some questions may be incomplete, unreasonable, or impossible to answer. When that happens risk assessors must tell the risk manager. If important questions are missing they should be added. Expect questions to be clarified, modified, deleted, and added to throughout the risk management activity.



As mentioned previously, not all questions are science questions. It may take more than a risk assessment to answer all of the risk manager's questions. Some activities may require legal analysis, benefit-cost analysis, consumer surveys, market assessment, and the like, and these kinds of analyses may be considered outside the purview of risk assessment in some circumstances.

At this point we are up to three important pieces of paper that are essential to the successful completion of the risk management activity. They are:

- A problems and opportunities statement
- An objectives and constraints statement
- A list of questions the risk manager would like answered

If you vet the contents of these three pieces of paper with your stakeholders, you have the beginnings of an excellent risk communication process. These three pieces of paper and the process you went through to prepare them also provide an excellent basis for the eventual documentation of your risk management activity.

### **3.3.2.5 Initiate the Risk Assessment**

With a decision to do a risk assessment in one hand and the questions to be answered by the assessment in the other, it is time to initiate the risk assessment. It is the risk manager's responsibility to provide the resources necessary to get the risk assessment done. In general, that means assembling an appropriate team of experts to carry out the task; providing them with sufficient time, budget, and other necessary resources; and interacting with them extensively enough to instruct them clearly on the information needed for decision making. All of this is to take place while maintaining a functional separation between risk assessment and risk management activities.

#### **FUNCTIONAL SEPARATION**

Functional separation means separating the tasks carried out as part of risk assessment from those carried out by risk management at the time they are performed. Some organizations may have separate offices to conduct the two tasks. In some situations, the same individual(s) may be responsible for management and assessment. This occurs most often in resource poor situations, but it may also occur with routine and simple issues.

It is important that safeguards be in place to ensure that management and assessment tasks are carried out separately of each other, even if they are performed by the same individuals. Management and assessment are fundamentally different. The objective assessment needs to remain objective and the subjective judgment needs to remain apart from it.

An independent interdisciplinary team of scientists, analysts, and other experts is preferred for conducting risk assessment. In routine situations, in-house experts and personnel are sufficient for a risk assessment team. In more structured or international environments, risk assessments may be carried out by an independent scientific



institution, an expert group attached to an institution, or an expert group assembled for the express purposes of the risk assessment.

Risk managers are responsible for supporting the work of the risk assessment team and other evaluations by ensuring that they have the necessary resources. In general, a good risk assessment policy will have established guidelines for much of this administrative work on a once-and-for-all basis before the actual risk assessment is initiated. The roles and responsibilities of key personnel, the manner in which different organizational units interact, milestones, methods for communicating and coordinating—all of these administrative matters are the responsibility of the risk managers.

### 3.3.2.6 Consider the Results of the Risk Assessment

After initiating the risk assessment, assessors go off and complete their work in a risk assessment, which is the subject of the next chapter. When the risk assessment is completed and submitted to the risk manager, the major question at this step in the risk management process is: “Did risk managers get answers to their questions that they can use for decision making?”

#### EXAMPLE OF RISK ASSESSMENT ROLES

The FDA’s Center for Food Safety and Applied Nutrition has established three unique positions to help with consistency, coordination, and making risk decisions. They are:

- Science Advisor for Risk Analysis
- Risk Analysis Coordinator
- Risk Assessment Project Manager

The risk assessment should clearly and completely answer the questions asked by the risk managers to the greatest extent possible. Those answers should identify and quantify sources of instrumental uncertainties in risk estimates and in the answers provided to risk managers. Whenever the uncertainty might affect the answer to a critical question and, consequently, the risk manager’s decision, or decision outcomes, this information must be effectively communicated. Hence, in addition to getting answers to their questions, risk managers must also know the strengths and weaknesses of the risk assessment and its outputs. [Chapter 19](#) is devoted to practical approaches to decision-making under uncertainty.

It is not necessary for the risk managers to understand all the details of the risk assessment, but they must be sufficiently familiar with the risk assessment techniques and models used to be able to explain them and the assessment results to external stakeholders. To understand the weaknesses and limitations of the risk assessment it is important to:

- Understand the nature, sources, and extent of instrumental knowledge uncertainty and natural variability in risk estimates.
- Understand how the answers to critical questions might be changed or how decision outcomes might vary as a result of this uncertainty.

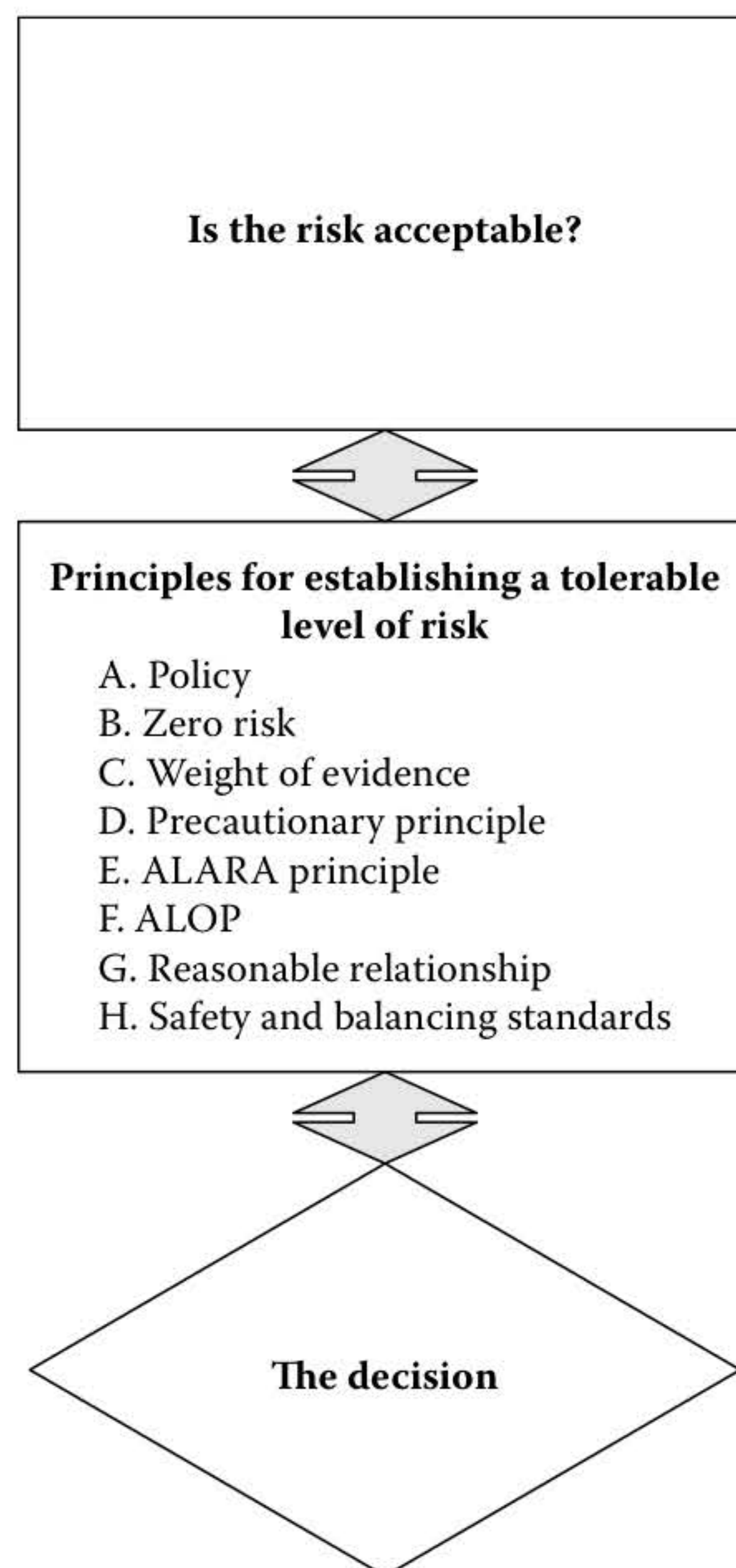


- Be aware of all important assumptions made during the risk assessment as well as their impact on the results of the assessment and the answers to the questions and the range of decision outcomes.
- Peer review may be a useful tool for discovering implicit assumptions of the risk assessment and other instrumental uncertainties that may have escaped the assessors' awareness.
- Identify research needs to fill the key data gaps in scientific knowledge to improve the results of the risk assessment in future iterations.

If the assessment has adequately met the information needs of the risk manager, it is complete. If the assessment has failed to provide the necessary information for any reason, another iteration of the assessment may be in order.

### 3.4 RISK EVALUATION

The risk assessment is now complete, and it is time to evaluate the risk following the steps shown in [Figure 3.4](#). Is the risk acceptable? This is the first significant decision



**FIGURE 3.4** Risk evaluation steps.



for the risk manager to make. It requires the risk manager to be able to distinguish two important ideas: acceptable risk and tolerable risk. An acceptable risk is a risk whose probability of occurrence is so small or whose consequences are so slight or whose benefits (perceived or real) are so great that individuals or groups in society are willing to take or be subjected to the risk that the event might occur. An acceptable risk requires no risk management; it is, by definition, acceptable. A risk that is not acceptable is, therefore, unacceptable and by definition must be managed.

### OPPORTUNITIES FOR GAIN

What is an acceptable uncertain potential gain? Does it make sense to talk about a tolerable level of such risk? It is impossible to anticipate every potential gain situation but for a vast majority of them the concepts of acceptable and tolerable risk hold up pretty well.

Let us consider the potential for economic gain as the endpoint. Acceptability is going to be defined by both the consequence, for example a net negative or net positive outcome, and its probability. A low probability of a large positive outcome may be acceptable while a high probability of a small positive outcome may not be, or vice versa. In situations where the combination of consequence and its probability are not acceptable, in a desirable sense, the risk can be managed to the point that it becomes tolerable. This is done by taking steps to increase the likelihood of a desirable outcome or by increasing the magnitude of the potential beneficial consequences.

Risk taking is essentially different from risk avoiding. Risk taking decisions are conscious decisions to expose one's self to a risk that could have otherwise been avoided. Consequently, managing uncertainty prior to decision making or during evolutionary decision making is a significant risk management strategy for opportunity risks.

It is conceptually possible to take steps to reduce an unacceptable level of risk to an acceptable level. More often than not, however, unacceptable risks are managed to tolerable levels. A tolerable risk is a nonnegligible risk that has not yet been reduced to an acceptable level, think of it as a subset of unacceptable risk. The risk is tolerated for one of three reasons. We may be unable to reduce the risk further; the costs of doing so are considered excessive; or the magnitude of the benefits associated with the risky activity are too great to reduce it further. A tolerable risk is not an acceptable risk, but its severity has been reduced to a point where it is tolerated.

If a risk is initially judged to be unacceptable, risk managers will seek to determine a level of risk that can be tolerated if the risk cannot be reduced to an acceptable level. Several principles (see [Figure 3.4](#)) have been used to determine a tolerable level of risk (TLR). Once a methodology for establishing the TLR is chosen, it is the risk manager's responsibility to determine the TLR as part of the risk evaluation activities. Very often, for example, the TLR is less an explicit determination than it is a default result of what it is possible to do. This determination overlaps considerably with subsequent risk control activities.



Bear in mind that risk managers are not, at this point, being asked to evaluate the effectiveness of any specific risk management options that may have been assessed in the risk assessment. That particular evaluation task is considered later under the risk control activities. It is also helpful to bear in mind that we are describing an iterative process in what amounts to a linear narrative. It will often be necessary to double back on the process and repeat a few steps. So, although the description here might suggest that the risk and all risk management options are assessed in a risk assessment that is then handed, complete, to risk managers, the real process is not always so simple.

### **INPUT AND FEEDBACK**

Determining what risk is acceptable and establishing a tolerable level of risk (TLR) for risks that are unacceptable are decisions that cannot often be made without input from stakeholders and the public. In some decision contexts this may require a rather extensive public involvement program. In others it may be a simple risk communication task. Offering opportunities for input and providing feedback on views about what is acceptable, unacceptable, and tolerable is a critical part of an effective risk communication program.

Determining whether a risk is acceptable or not is a matter of subjective judgment. It is not a scientific determination. There is potential for the uncertainty about the best decision to make to increase at this point if the risk manager's information does not include the views of key stakeholders or if the risk communication program has not yet provided these stakeholders with opportunities for input and feedback. It is usually important to understand the risk attitudes of key stakeholders when establishing a TLR. The principles described in the following section can be used to help determine whether the assessed risk is acceptable or not. They can also be used to find a TLR when the risk is unacceptable.

#### **3.4.1 PRINCIPLES FOR ESTABLISHING ACCEPTABLE AND TOLERABLE LEVELS OF RISK**

There is no magic bullet to be found in this section. Deciding whether an assessed risk is acceptable or not and determining a tolerable level of risk for risks that cannot be rendered acceptable are fundamentally searches for subjective targets. Does the risk manager seek the highest possible level of protection, a desirable level of protection, an achievable level of protection, or something that is practical (implementable) or affordable? Does equity matter? Must there be a consistent level of protection, or is the economic efficiency of a level of protection more important? There is no one answer that will satisfy everyone. Therefore, the process by which this decision is reached may be as important as the decision rule that is used to reach it. To determine an acceptable or tolerable level of risk, managers must take into account the scientific evidence, the uncertainty, and the values evident in their objectives and constraints. Several principles used by risk managers are reviewed here briefly.



### 3.4.1.1 Policy

Some decisions have already been made for the risk manager by persons higher in the decision-making hierarchy. These may be the owners of a company, upper management, Congress, the president, or other elected officials. In the United States, for example, Congress and the president may pass authorizing legislation that prescribes what an agency can and must do. In that case, the risk manager's job is to figure out the best way to do it.

#### THE DELANEY CLAUSE

The Delaney clause is a part of the 1958 Food Additives Amendment (section 409) to the 1954 Federal Food, Drug, and Cosmetic Act (FFDCA). This clause governs regulation of pesticide residues in processed foods. It establishes that no residues from pesticides found to cause cancer in animals will be allowed as a food additive. This means that tolerance levels must be based only on the risk of carcinogenicity and that the benefits of the pesticide may not be considered. This clause was considered, at the time, to have set a zero-risk standard.

Some risk issues may be resolved by a court decision. Decision contexts initiated as a result of administrative or other legal proceedings are often circumscribed by the entity that orders the decision action. Courts at all levels of jurisdiction are increasingly being drawn into policy decisions that could affect the principles for determining an acceptable or tolerable risk.

Decisions made in the public sector, especially by agencies and organizations acting as stewards of a public asset or trust, will often be constrained by policy. Working with a government agency often means dealing with their policy restrictions and requirements. International treaties and agreements may also identify solutions or limit options. In the private sector, acceptable and tolerable levels of risk may be established in an entity's risk appetite or risk tolerance, which are topics discussed in [Chapter 6](#).

### 3.4.1.2 Zero Risk

Banning risky activities has been a popular approach in years gone by. Making actions that involve any risk at all taboo and declaring them forbidden has been tried in the past when it was once possible to imagine zero risk. Years ago, the limits of our knowledge and of scientific detection made it possible to find comfort in laws that appeared to legislate safety as a matter of zero risk. See the Delaney clause text box for an example.

By the middle of the 1980s, decision makers began to abandon the notion of zero risk in favor of more realistic versions of negligible risk. The one-in-a-million standard seems to have captured our imagination early. This evolved from and morphed into a notion of de minimis risk, a numerical value of risk too small to be bothered about. You can think of negligible and de minimis as “practically zero” without doing any real damage to the concepts.



Society and policy makers have, by and large, abandoned the idea that zero risk is a realistic measure of acceptable risk. Establishing a level of *de minimis* risk remains a viable concept for determining acceptable and tolerable levels of risk in certain settings.

### DE MINIMIS RISK

A careful reading of official documents about the *de minimis* principle, as well as of relevant journal articles, shows that it is usually explained along one of the following three formulations. The specific-number view says a risk is *de minimis* provided its probability falls below a certain number, for example,  $10^{-6}$ . The nondetectability view says a risk is *de minimis* provided it cannot be scientifically established whether the risk has in fact materialized or not. The natural-occurrence view for an anthropogenic risk says a risk is *de minimis* provided its anthropogenic risk does not exceed the natural occurrence of this type of risk.

*Source:* Peterson 2002.

#### 3.4.1.3 Weight of Evidence

We tend to like once-and-for-all resolution of problems on the basis of compelling scientific evidence. In an uncertain world, the truth is not always easy to see. Data gaps and conflicting evidence often obfuscate risk management decisions. In a weight-of-evidence approach to evaluating risk, risk managers assess the credibility of conflicting evidence about hazards and risks in a systematic and objective manner. A formal weight-of-evidence process may rely on a diverse group of scientists to examine the evidence to reach consensus views. The evidence must be of sufficient strength, coherence, and consistency to support an inference that a hazard and a risk exist.

Evaluating the weight of evidence is an ongoing activity that attempts to balance positive and negative evidence of harmful effects based on relevant data. Thus, the evaluation of risk is conditional on the available evidence and subject to change as new evidence becomes available. When there is uncertainty about the nature of a risk, a weight-of-evidence approach may be useful in establishing whether it is acceptable or tolerable.

#### 3.4.1.4 Precautionary Principle

Precaution may be described in this context as refraining from action if the consequences of the action are not well understood. It is prudent avoidance. The precautionary principle is broadly based on the notion that human and ecological health are irreplaceable human goods. Their protection should be treated as the paramount concern for regulatory organizations and government. All other concerns are secondary.

The precautionary principle is controversial and heavily influenced by culture and uncertainty. In a very loose and informal sense, the precautionary principle suggests that when there is significant uncertainty about a significant risk, we should err on the side of precaution, if we are to err at all. That means that activities that could give rise to catastrophic outcomes should be prohibited. It also means that if inaction could give



rise to catastrophic outcomes, we should act, not wait. The precautionary principle is generally considered to be most appropriate in the early stages of an unfolding risk problem, when the potential for serious or irreversible health consequences is great, or when the likelihood of occurrence or magnitude of consequence is highly uncertain. The desire for precaution is usually positively related to the amount of uncertainty in a decision problem. The precautionary principle can be invoked for decision making when uncertainties are large or intractable.

#### **WINGSPREAD STATEMENT**

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the precautionary principle must be open, informed, and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action

**Wingspread Conference, January, 1998**

#### **3.4.1.5 ALARA Principle**

ALARA is an acronym for As Low As Reasonably Achievable. Technology and cost present two realistic constraints on what it is possible to achieve in terms of risk reduction. If a risk is not yet as low as is reasonably achievable, it is not acceptable according to this principle. One popular criterion for establishing a tolerable level of risk is to get risk as low as we are capable of making it. Then what choice do we have but to tolerate the risk that remains?

Sometimes the ALARA principle is used to take risks even lower than an acceptable level of risk. Minimizing risks even below levels that would be acceptable is sometimes justified based on the presumption that what constitutes “acceptable risk” can vary widely among individuals.

Best available technology (BAT) is a related concept. It differs in a potentially significant way, however, as BAT says to use the best available with no further qualification. ALARA introduces the idea of reasonableness, and this opens the management door to the consideration of other factors like cost and social acceptability. BAT does not consider these other factors.

#### **3.4.1.6 Appropriate Level of Protection**

An appropriate level of protection (ALOP) defines or is defined by the risk society is willing to tolerate. Despite the promising sound of this principle, it is little more than circular reasoning because it presumes one has found a way to identify the holy grail of what is “appropriate” for society. In fact, it is often little more than a statement of the degree of protection that is to be achieved by the risk management option implemented. Policy (see text box) or a rigorous public involvement program provide alternative ways to define the ALOP.



### ALOP EXAMPLE

The commitment of FDA, FSIS, and CDC to reduce foodborne listeriosis was formally reaffirmed as a national public health goal in the Healthy People 2010 initiative coordinated by the United States Department of Health and Human Services (US DHHS). The federal government established a goal of working with industry, public health, and research communities to achieve an additional 50% reduction in listeriosis by 2010

**FDA, 2003**

The significant contribution of this concept is that it flips the focus from risk to protection, where we might think of protection as akin to different degrees of safety. The factors used to determine an ALOP typically include:

- Technical feasibility of prevention and control options
- Risks that may arise from risk management interventions
- Magnitude of benefits of a risky activity and the availability of substitute activities
- Cost of prevention and control versus effectiveness of risk reduction
- Public risk reduction preferences, that is, public values
- Distribution of risks and benefits

#### 3.4.1.7 Reasonable Relationship

This principle suggests that costs of risk management should bear “a reasonable relationship” to the corresponding reductions in risks. It is not a benefit-cost analysis but it is an attempt to balance nonmonetary benefits (i.e., risk management outputs and outcomes) and the monetary costs of achieving them. Cost effectiveness and incremental cost analysis are often used as the basis for determining the reasonableness of this relationship.

#### 3.4.1.8 Safety and Balancing Standards

Safety maintains deep roots within the risk analysis paradigm. A great many safety standards have been used to establish the tolerable level of risk. Safety standards encompass a bundle of standard-setting methods that rely ultimately on some degree of subjective judgment. For example, the zero-risk standard mentioned previously is one possible safety standard. Zero just happens to be one of many potential thresholds that can be established to define safety. Any nonzero level of risk can be stipulated as safe, acceptable, or tolerable. In fact, TLR has been dangled as one such tantalizing threshold standard in some of the literature. If we could develop a TLR for dam safety or for food safety or for transportation modalities, policy making would be much easier.

Many determinations of a TLR require a subjective balancing decision. Risks of uncertain potential gain or benefits may be best served by using some type of balancing standard. For example, risk-benefit trade-off analysis generally implies that greater benefits mean we are willing to accept a greater level of risk in exchange



for those benefits. The risk-benefit trade-off may explain why we are all willing to assume the risk of driving in a modern society.

Comparative risk analysis (CRA) ranks risks for the seriousness of the threat they pose. It began as an environmental decision-making tool (USAID 1990, 1993a,b, 1994; EPA 1985, 1992a,b, 1994; World Bank 1994) used to systematically measure, compare, and rank environmental problems or issues. It typically results in a list of issues or activities ranked in terms of relative risks. The most common purpose of comparative risk analysis is to establish priorities for a government agency. The concept is perfectly adaptable to any organization.

Benefit-cost analysis is another kind of balancing standard used to determine what is acceptable or tolerable by attempting to identify and express the advantages and disadvantages of a risk or risk management option in dollar terms. It is considered a useful measure of economic efficiency.

In addition to threshold and balancing standards, procedural standards are sometimes used to define what is acceptable or tolerable. Procedural standards typically identify an agreed upon process, which is often the result of negotiation or a referendum of some sort. If the agreed-upon process is followed, then the results of that process are considered acceptable or at least tolerable.

### 3.4.2 THE DECISION

If the assessed risk is judged by any one of these or any other method to be acceptable, there is little more for the risk manager to do. However, an unacceptable risk must be managed. The ideal would be to manage it to an acceptable level, and when that cannot be done it should be managed to a tolerable level. There are six broad strategies for managing risk. These are:

1. Risk taking
2. Risk avoidance
3. Reduce the probability of the risk event (prevent) and increase the probability of a potential gain (enhance)
4. Reduce the consequence of the risk event (mitigate) and increase the consequence of a potential gain (intensify)
5. Risk pooling and sharing
6. Retain the risk.

#### **NO ONE SPEAKS THIS CAREFULLY**

Beware. I have gone to some effort to try to carefully differentiate risk management strategies in the text. In my experience no one speaks quite this carefully. In fact, mitigation, management, control, treatment, avoidance, prevention, and probably several other terms are all used interchangeably. So, if you take pains to speak carefully and precisely, do not assume others hear you with the same precision. Take the time to clarify your meanings.



Risk managers may choose to take a risk when it presents an opportunity for gain that is acceptable or at least tolerable. When it comes to losses with no chance of gain, it is usually preferable to avoid such a risk whenever possible. If avoidance is not practical, we can try to manage either or both of the two dimensions of risk. Risk prevention reduces the likelihood of exposure to a hazard or otherwise reduces the probability of an undesirable outcome. Conversely, efforts can be made to increase the likelihood of gain from an opportunity risk. This is an enhancement strategy.

Risk mitigation allows that risky events will occur, so it seeks to reduce the impact of the risk by reducing the consequences of the event. Increasing the magnitude of a potential positive consequence, namely intensification, is another opportunity risk management strategy. A fifth option is to pool the risks into a larger group and share these risks over a greater spatial or temporal extent. A sixth strategy is to retain the risk. When no viable option for managing the risk can be found, we have no option but to put up with the risk as is. As this does nothing to lessen the risk or its impacts, some would not call it a strategy for managing risk.

If the risk manager's role in the risk assessment can be described as a positive one, then the manager's role shifts to a normative one in these risk evaluation tasks. Here the risk manager describes the world as it "ought" to be. This is a subjective deliberative decision. This normative role continues into the manager's risk control responsibilities.

### **3.5 RISK CONTROL**

Presuming the risk has been judged to be unacceptable during risk evaluation, the risk manager's job now becomes reducing the risk to an acceptable or tolerable level. Risk control is a term of art used to avoid greater confusion with the risk management strategies described previously. It may be misleading to suggest that we can control some risks. It may be more honest to say that we struggle to manage them. However, calling this risk management activity "risk management" might cause even greater confusion. So be forewarned not to interpret control too literally in the current context, risk treatment is a synonym. The basic tasks during this risk control phase of the manager's job are shown in [Figure 3.5](#).

The extent to which the public and stakeholders are engaged in this phase may show the greatest range of variation of any risk management activity. Private risk management decisions may not involve anyone outside the organization. Collective decision-making processes can involve extensive public involvement programs for the risk control activities.

#### **3.5.1 FORMULATING RISK MANAGEMENT OPTIONS**

What does success look like? Risk management options (RMOs) are strategies that describe specific ways your risk management objectives can be achieved. These strategies are subordinate to your objectives. An RMO is relevant only to the extent that it helps you meet your objectives. Best-practice risk management recognizes that objectives can be achieved in a variety of ways and formulates alternative strategies that reflect these different ways.



### **THE PROBLEM IS WE NEED A LEVEE**

Many problems are initially identified in terms of a solution. Risk analysis focuses on getting the problem right. The problem may be flooding, it may be unrestricted land development or any other number of things. A levee is one possible solution. It is common for many problem-solving processes to begin with someone identifying the solution before the problem is clearly identified. Keep track of and consider that solution but do not let it prevent you from identifying alternative means of achieving your objectives or from properly identifying the problem.

Laws, authorities, policies, budget priorities, and politics may limit what you can actually do. None of these should limit the things you think, however. Formulate RMOs comprehensively and creatively without respect to any limitations. Thinking creatively and comprehensively about solutions to risk problems is one area in which there is room for substantial improvement for many organizations. Getting risk managers to consider a broad array of risk management options has not been the easiest thing to do. One major reason for this is that we tend to favor solutions we are familiar with or that we have the authority and ability to act upon. There is a certain obvious appeal to this sort of thinking.

If there is an effective way to manage a risk that your organization cannot implement, others may implement it voluntarily if the idea is good enough. Or perhaps there are ways to motivate those who can implement a good idea to do so. Bear in mind that good ideas for achieving worthy objectives are valid reasons for organizations to be granted new authorities.

RMOs may be formulated by the risk analysis team with input from stakeholders and decision makers. They may be imposed from above by higher authorities. They may be suggestions from the public or new scientific or technological developments. The ideas can come from Congress, agency staff, industry, government officials at all levels, academia, “the public,” television, science fiction, your left frontal lobe, or a bottle of beer. They are the children of perspiration, inspiration, and imitation. An RMO may be proposed at any point in the risk management process. Some processes may begin because someone has framed a problem (incorrectly, I hasten to add) in terms of a solution.

The process of identifying RMOs is simplified by considering a few option formulation steps. If risk managers have done a good job identifying objectives and constraints, the simplest way to begin is to identify measures that could achieve each objective. A measure is a feature that constitutes part of a strategy or RMO. Think of a feature as some physical change or an activity, where an activity is a change in the way we do something. So, for objective 1, we identify as many measures that could contribute to this objective as possible, then repeat this process for each objective and constraint.

Second, you formulate or construct RMOs from these measures. Think of the measures as building blocks and RMOs as the “structures” you build to solve problems and attain opportunities.



The third step is to reformulate RMOs. Like the rest of the risk management process, RMO formulation is iterative. Once an option is formulated, see if you can refine it. When evaluation of the options begins, it can be very effective to reformulate or tweak the options to improve their performance.

### KEY POINT

When developing RMOs, quantity counts more than quality in the initial stages. You cannot be sure you have the best option unless you have considered many options. Avoid the temptation to fall in love with your first idea. Formulating alternative RMOs is an essential step in good risk management.

How do you know when a set of measures is an RMO? A good RMO should be complete, effective, efficient, and acceptable. *Completeness* means all the necessary pieces are accounted for and included in the option. *Effectiveness* means the mix of measures meets the objectives as well as possible and avoids violating constraints as much as possible. *Efficiency* means there is no less costly option that produces the same benefits and benefits cannot be increased without increasing costs. Neither can adverse effects be decreased without decreasing benefits or increasing costs. *Acceptability* means no laws or regulations are violated and there is no evident reason why the RMO could not be implemented.

### 3.5.2 EVALUATING RISK MANAGEMENT OPTIONS

Earlier we spoke of evaluating the risks that are assessed in the risk assessment. Don't confuse that with evaluating the risk management options that are being considered for use in managing unacceptable risks to a tolerable level. In some cases, the performance of these RMOs may have been assessed simultaneously with the risks themselves in the risk assessment. In other situations, RMOs will not even be identified until after the risk assessment is completed. The actual sequence of events can vary with the nature of the risk and the available information in any given decision context.

No matter which sequence your own risk management activity might follow, there comes a time when the formulation of RMOs is complete enough that you need to begin to evaluate these ideas. This is part of the nonscientific work of the risk management process. Values, beliefs, and biases all enter the process here, and appropriately so. This is where risk managers begin to weigh their decision options and earn their pay.

After RMOs have been comprehensively formulated, to get from a number of options to the best option you must:

- Evaluate options
- Compare options
- Make a decision (select the best option)

These can be discrete steps or they may be all mixed together. Like other risk management responsibilities, these can be iterative tasks. Up until now, the emphasis



has been on generating as many serviceable ideas for managing an unacceptable risk as are possible. Only now do we begin to go through those ideas and evaluate them to judge which are viable solutions and which are not.

Evaluation of RMOs is a deliberative analytical process. Evaluation and comparison require measurements of evaluation and comparison criteria. These will be produced by risk assessors and other analysts at the direction of risk managers. In evaluation, risk managers look at each RMO individually and consider it on its own merits. Think of this evaluation step as a pass/fail decision that qualifies some options for serious consideration for implementation as a solution and rejects others. One of the simplest ways to evaluate an RMO is to examine the effects it would have on the risk management objectives and constraints. The underlying presumption, once again, is that if we achieve our objectives and avoid violating the constraints, we will solve our problems and realize our opportunities. That is our definition of a successful risk management process.

It is, of course, common practice to focus carefully on the management of risks during the evaluation process. In a good risk management process, risk reduction can be expected to be prominently displayed among the risk management objectives.

The effects of an RMO can be identified by comparing two scenarios as shown in [Table 3.1](#). Identifying the existing levels of risk, also known as inherent risk, defines one scenario. Reestimating those risk levels with an RMO in place and functioning, that is, residual risk, is the second scenario. The differences between these scenarios can be attributed to the efficacy of the RMO, all other things being equal. [Table 3.1](#) shows a hypothetical evaluation using a scenario without any additional risk management activity (without) and a scenario with a new RMO in place (with) as the basis for the evaluation.

There are currently 50,000 illnesses and implementing RMO 1 will reduce that total to 20,000. The change is a reduction of 30,000 illnesses. The changes are what the risk managers will evaluate. If the objectives and constraints were to reduce adverse health effects, minimize costs, and avoid reductions in benefits and job losses, then a subjective judgment needs to be made about whether this particular option does this in a manner satisfactory enough to warrant serious consideration for implementation as a solution. The process is repeated for each individual RMO. All scenario comparisons would use the same “without” condition scenario as the starting point. The “with” condition scenario will vary from one RMO to another.

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**TABLE 3.1**  
**Evaluating an RMO via Comparison Scenarios without Additional Risk Management and with Additional Risk Management**

| Effect           | Future Without | Future With   | Change         |
|------------------|----------------|---------------|----------------|
| Annual illnesses | 50,000         | 20,000        | –30,000        |
| Cost             | \$0            | \$150 million | +\$150 million |
| Benefits         | Unchanged      | Reduced       | Decrease       |
| Jobs             | Unchanged      | Lose 2,000    | –2,000         |

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Uncertainties affecting estimates of the evaluation criteria must be considered at this step. For simplicity, the values presented in [Table 3.1](#) are shown as point estimates. In actual fact they may be probabilistic estimates reflecting varying degrees of natural variability and knowledge uncertainty.

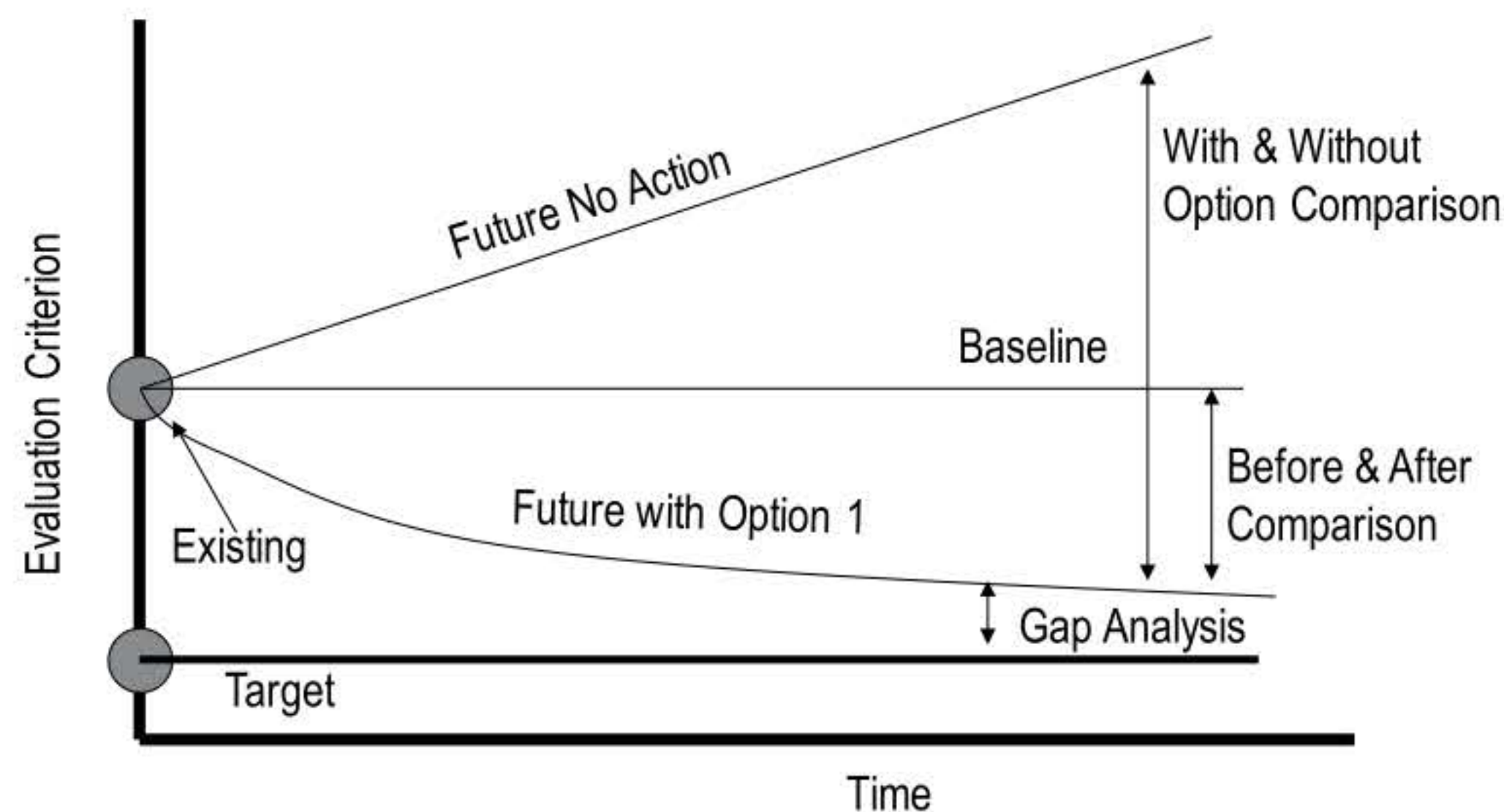
Note that an option is not being compared to other options at this point. We are simply separating our RMOs into two piles. One pile “qualifies” for serious consideration for implementation and the other pile does not. The reject pile can either be reformulated to improve their performance or dropped from further consideration. The qualified RMOs will later be compared to one another.

Evaluation requires evaluation criteria. The risk management objectives and constraints are a logical source of such criteria, but risk managers are free to evaluate on any basis that serves their decision-making needs. At times the evaluation criteria may be a subset of the objectives and constraints or a set of criteria quite different from them. The risk manager’s role in evaluation includes identifying evaluation criteria and selecting qualified plans. The selection of these plans for further consideration is sometimes delegated to the assessors, as this is a screening decision. Assessors analyze the RMO’s contributions to the evaluation criteria for the managers.

### 3.5.2.1 Comparison Methods

Evaluating plans requires a comparison of evaluation criteria values without and with an RMO in place. To generate estimates of the effects of an RMO, some sort of comparison method is required. There are at least three different ways to compare scenarios: gap analysis, before-and-after comparison, and with-and-without comparison. The latter is generally preferred as the most objective comparison, and it is recommended for generating measurements for evaluating the impacts of an RMO. The three methods are shown in [Figure 3.6](#) and described below. This comparison of evaluation criteria for a specific RMO is distinct and different from the comparison of alternative RMOs.

An evaluation criterion can be anything relevant to risk managers for this task. A common first step in evaluation is to describe the baseline condition of this criterion estimate. The baseline measure is often assumed to be the existing level of the criterion over time with no change. The “without” condition describes the most likely future condition of the evaluation criterion in the absence of any intentional change in risk



**FIGURE 3.6** Three methods for comparing scenarios.



management. This scenario shows the future criterion values without additional risk management. Every RMO is to be evaluated against this same “without” condition to estimate its effect on the criterion.

The “with” condition describes the most likely future condition of the evaluation criteria with a specific RMO in place. Each intervention (e.g., RMO 1) has its own unique “with” condition. Therefore, RMO 1 will have a different “with” condition than RMO 2, and so on.

The best evaluation method compares the “with” and “without” condition levels of the evaluation criteria for each RMO. The resulting analysis provides values like those shown in [Table 3.1](#). These values serve as the basis for qualifying an RMO for further consideration or not.

Note that the before-and-after comparison, popularized by the National Environmental Policy Act (NEPA) process and also quite common in the food safety and some public health fields, could yield significantly different insights about the efficacy of an RMO. There are several definitions of gap analysis. Here, gap analysis refers to the difference between a prescribed target level of a criterion (or other effect) and what you are able to attain in reality. This graphic represents a hypothetical example to illustrate the concept; other trends in the scenarios are possible.

### 3.5.3 COMPARING RISK MANAGEMENT OPTIONS

A good RMO formulation process will produce numerous alternative solutions to a problem. A successful evaluation process will identify several of these as viable solutions. At this point it is necessary to compare the qualified solutions to identify the best one from among them. Comparison is an analytical step. It means establishing the similarities and dissimilarities among RMOs and contrasting the merits among them. Making a decision is based on weighing the differences among the compared RMOs such as those shown in [Table 3.2](#).

A good comparison process identifies differences among the RMOs that matter to people. It also makes the trade-offs among the options clear. A simplified example of a comparison summary is shown in [Table 3.2](#). For simplicity, it ignores the complication of expressing uncertainty about these estimates. It is important to understand that uncertainty may be an essential part of an actual comparison. Each column represents

**TABLE 3.2**  
**Comparing RMOs by Contrasting the Differences in their Effects on Decision Criteria**

| Effect              | RMO1           | RMO2           | RMO3           |
|---------------------|----------------|----------------|----------------|
| Annual illnesses    | −30,000        | −40,000        | −10,000        |
| Illnesses remaining | 20,000         | 10,000         | 40,000         |
| Cost                | +\$150 million | +\$500 million | +\$100 million |
| Benefits            | Decrease       | Decrease       | No change      |
| Jobs                | −2,000         | 0              | −500           |



a risk management option that has been qualified by the evaluation process. The rows represent decision criteria that have been identified as important to decision makers.

Table 3.2 shows how different RMOs make different contributions to the risk management objectives (assuming, for convenience, that they are reflected in the criteria chosen). RMO 2 reduces the number of illnesses more than any other option does. It also costs more. A summary table like this enables decision makers to see the differences among the options, and it makes the trade-offs more evident. Again, you are cautioned that these determinations are more difficult to make when the uncertainties in these estimates are reflected. Methods for doing this are discussed in later chapters.

Risk managers will direct the comparison process, although they will not usually do the supporting analysis. A critical management step is identifying the criteria to be used in the comparison. It is not unusual for risk assessors to suggest criteria and their metrics in unique situations. The comparison provides the analytical summary of the information that will form the foundation for a final decision. Thus, the risk manager's main role in comparison is often to request and understand the information that will be used to make a decision.

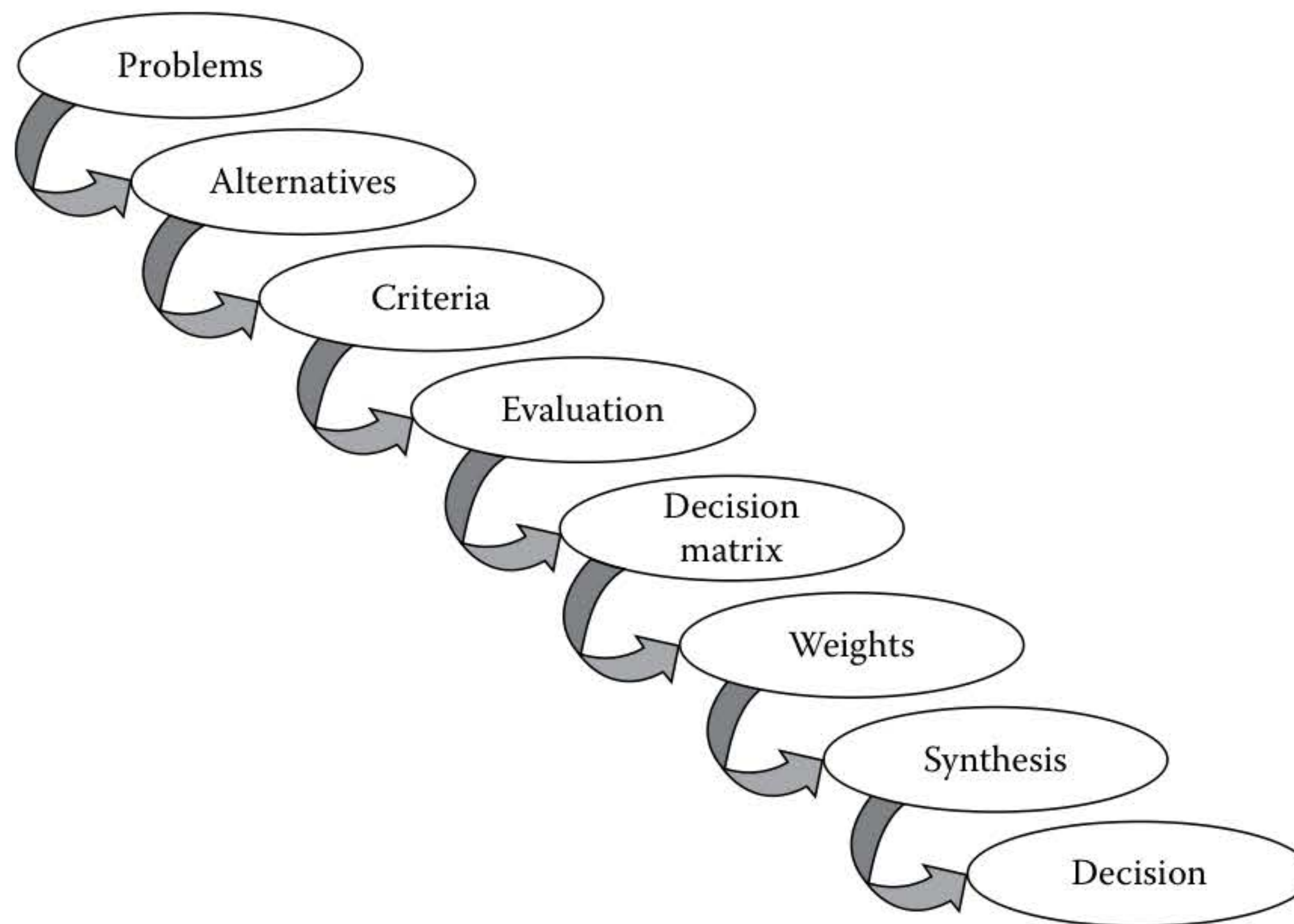
Comparisons are easiest when all effects can be reduced to a single, common metric. This, conceptually, could be lives saved, illnesses prevented, jobs created, or any metric at all. In benefit-cost analysis, that common metric is monetary. Many, if not most, comparisons involve incommensurable metrics. These situations will involve trade-off techniques. Those techniques can range from simple ad hoc decisions to sophisticated multicriteria decision analysis techniques. An example of the latter follows.

### 3.5.3.1 Multicriteria Decision Analysis

A decision is always easier to make when you consider only one dimension of the problem and when you are the only decision maker. Risk management decisions, however, are often complex and multifaceted. They can involve many risk managers, each with a different responsibility for the RMO, as well as stakeholders with different values, and priorities. They often involve complex trade-offs of risks, benefits, costs, social values, and other impacts because of the values in conflict as a result of the many perspectives represented by the stakeholders to a decision. One of the most predictable sources of uncertainty in any public decision-making process and in many private ones is what importance or weights should be assigned to the decision criteria. Multicriteria decision analysis (MCDA) is a bundle of techniques and methodologies that enables analysts to reduce the varied effects of different RMOs to a single utility metric that enables more direct comparison. Figure 3.7 shows the steps in a typical MCDA process (Yoe 2002). Through the evaluation step in the figure, this process tracks closely with the risk management process described here. What MCDA adds is a useful methodology for comparing options.

Multicriteria decision problems generally involve choosing one of a number of alternative solutions to a problem based on how well those alternatives rate against a set of decision criteria. The criteria themselves are weighted in terms of their relative importance to the decision makers. The overall "score" of an alternative is the weighted sum of its ratings against all criteria. The ultimate value of MCDA, both as a tool and a process, is that it helps us to identify and understand conflicts and the trade-offs they involve.

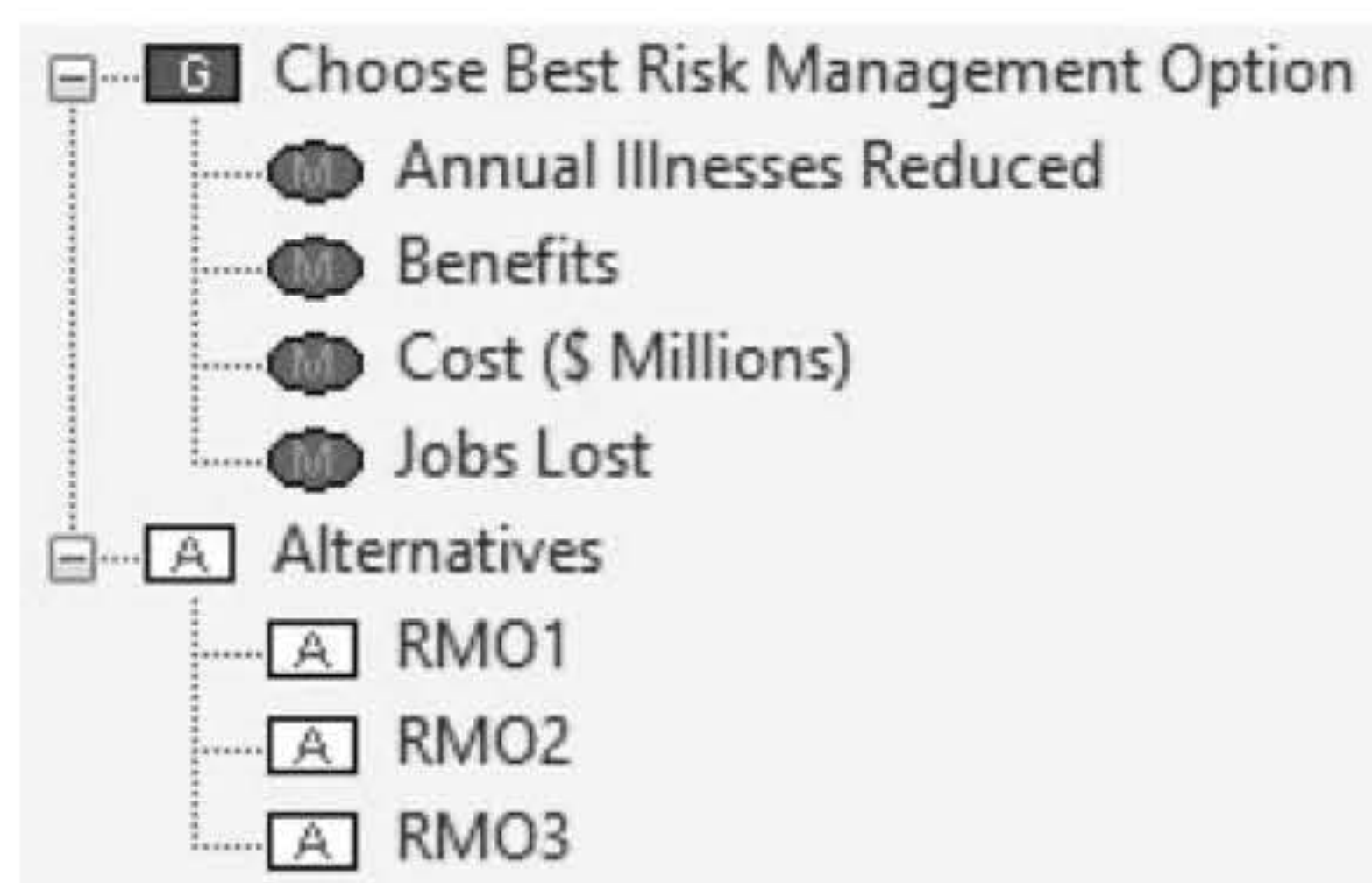




**FIGURE 3.7** MCDA process.

A risk management activity defines the problem and, done well, fits the MCDA process neatly. It provides alternative means to solve the problem. Decision criteria are identified, quite possibly, from the objectives and constraints during the evaluation and comparison processes. The last four steps of a generic MCDA process are often executed by a variety of user-friendly software tools.

A simple example based on the comparison in [Table 3.2](#) is illustrated in the following discussion using Logical Decisions.\* The process begins with a simple model as shown in [Figure 3.8](#). At the top is the decision objective. In the middle are the four criteria that will be used to make the decision, and alternative solutions are shown on the bottom.



**FIGURE 3.8** A simple MCDA model.

\* Trademark product of Logical Decisions.



Are the computed weights OK?

|                                              | Least Preferred Level | Most Preferred Level | Scaling Constant (Weight) |
|----------------------------------------------|-----------------------|----------------------|---------------------------|
| Annual Illnesses Reduced Measure (new units) | 10000                 | 40000                | 0.364                     |
| Cost (\$ Millions) Measure (new units)       | 500                   | 100                  | 0.273                     |
| Benefits Measure (labels)                    | Decrease              | Increase             | 0.182                     |
| Jobs Lost Measure (new units)                | 2000                  | 0                    | 0.182                     |

**FIGURE 3.9** Assigning subjective weights to MCDA decision criteria.

**TABLE 3.3**  
Consolidated SMART Rating for Each of Three Risk Management Options

| Risk Management Option | Option Score |
|------------------------|--------------|
| RMO 1                  | 0.481        |
| RMO 2                  | 0.545        |
| RMO 3                  | 0.500        |

Someone must specify the relative importance of the four criteria in the decision-making process. In the hypothetical example shown in [Figure 3.9](#), assume that the weights shown reflect the decision makers' preferences. Illnesses reduced received 100 points, cost got 75 points, and the remaining criteria got 50 points each. When normalized over the [0,1] interval the weights are as shown.

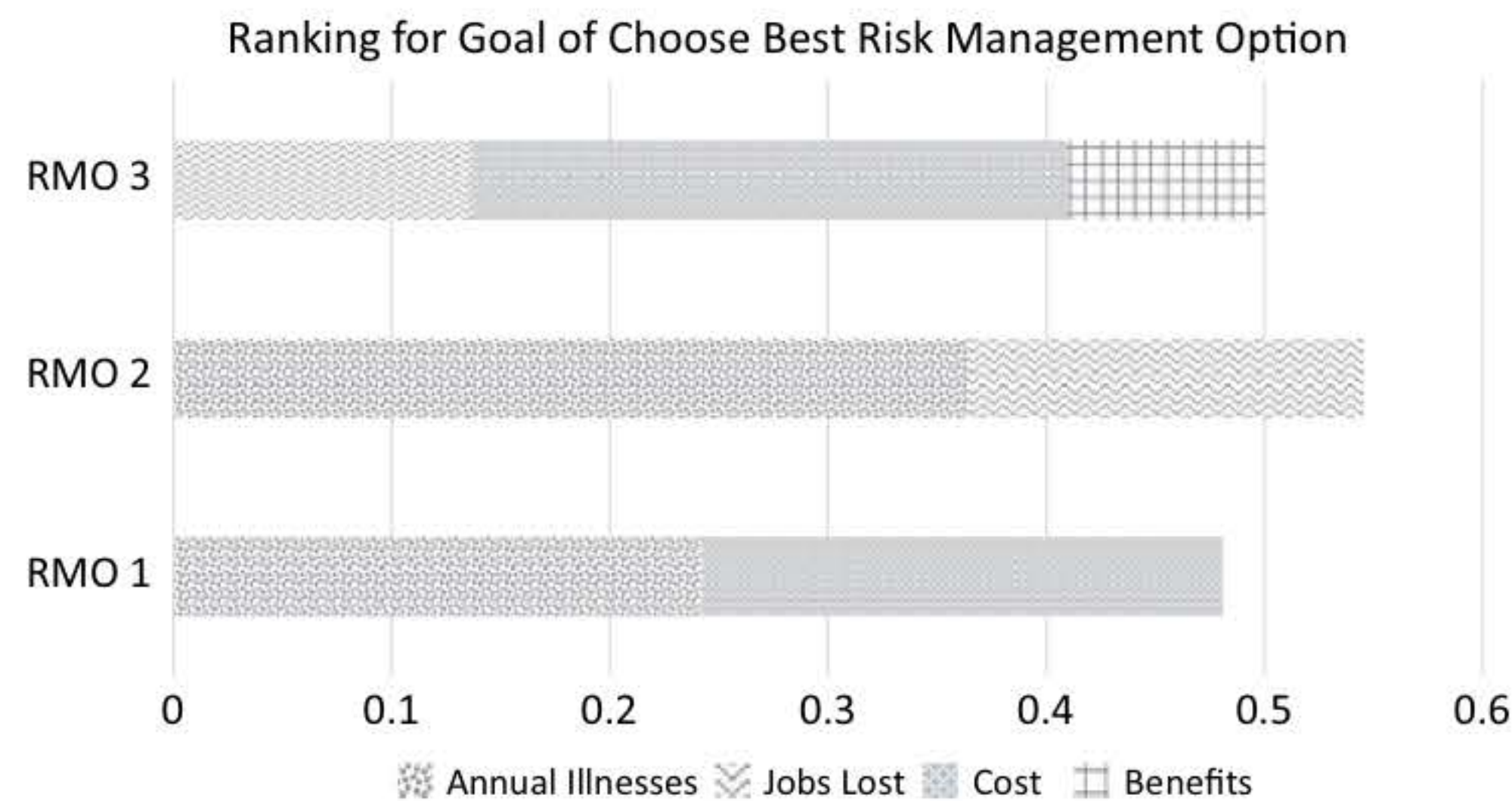
Measurements for each alternative's contribution to each criterion are also entered. These are simply the data from the comparison in [Table 3.2](#). The MCDA process can accommodate estimates of the uncertainty in these values although they are not used in this example. The weights assigned by the risk manager and criteria values developed by the assessors are combined using the Simple Multi-Attribute Rating Technique (SMART) to produce scores for the three RMOs, as shown in [Table 3.3](#).

RMO 2 is the "best" RMO based on chosen criteria, the available data, and their relative weights. [Figure 3.10](#) illustrates the trade-offs visually. RMO 2 makes the most positive contribution to two of the criteria. It is the worst on cost. MCDA does not produce answers or decisions. It produces information that can be helpful in identifying strengths and weaknesses of alternatives in light of the social values expressed in the analysis. It can be a valuable addition to a comparison process.

### 3.5.4 MAKING A DECISION

Choosing the best risk management option is the risk manager's next decision. This should be done only after taking the remaining instrumental uncertainties attending





**FIGURE 3.10** Contribution of options to decision criteria.

each risk management option into account. [Chapter 19](#) presents practical methods for making decisions under uncertainty.

If the uncertainty, for any reason, is significant enough to affect the nature of the answers to the risk manager's questions, to affect the choice of a course of action, or to affect the outcome of a decision, risk managers should carefully address that circumstance. That might be done through additional research, another iteration of the risk assessment, decisions phased to take advantage of the gradual resolution of key uncertainties, or an adaptive management approach to risk management.

The risk manager's role in the evaluation and comparison tasks is likely to be limited to deliberation. Risk assessors and others will do the relevant analysis. Making a decision based on the work done in these steps will usually be the risk manager's responsibility. In some decision contexts, the ultimate decision makers may be elected leaders or other personnel removed from or above the risk management process. Even in these instances, however, it is usual for risk managers to make a recommendation based on their experience and intimate knowledge of the problem.

### ADAPTIVE MANAGEMENT

Adaptive management is a risk management strategy that is useful when significant uncertainties can be expressed as testable risk hypotheses. Although there are many definitions it usually consists of a series of steps that include the following:

- Identify known uncertainties at the time a decision is made.
- Include experiments that can be used to test hypotheses about the known uncertainties among the design features in the RMO.
- Measure and monitor the results of the experiments to test the identified hypotheses.
- Modify predictive models based on what is learned.
- Use the revised models to identify adjustments to the RMO actions over time to increase the likelihood that management objectives will be attained.



Adaptive management means that actions are taken to both learn about and at the same time manage the risks of interest. *Adaptive Management: The U.S. Department of the Interior Technical Guide* is an excellent resource available online (USDOl, 2009).

Risk management as described in this chapter is an iterative screening process based on scientific and other criteria. Making a decision, specifically, selecting a recommended RMO, is the final screening activity for a given risk management activity. It is in the risk control activities that the risk manager's job shifts from the normative role of describing the world as it ought to be to taking action, which is the policy dimension of the risk manager's job.

It is not unusual for some organizations to rely on default decision rules. For example, some businesses will choose the option with the minimum payback period. Doing nothing is sometimes the default action for an organization, especially one affected by the National Environmental Policy Act (NEPA). It is a safeguard that attempts to ensure that any action taken is preferable to taking no action at all.

The manner in which decisions are made cannot be fairly generalized; they will vary from organization to organization, and even within an organization they may vary from situation to situation. Good decisions are strategic; they meet objectives, avoid constraints, solve problems, and attain opportunities. Selecting an RMO is, to the extent that the RMO establishes a residual risk level, equivalent to choosing a TLR. Alternatively, there may be instances where a TLR is determined first and then RMOs are formulated to attain that specific level of risk. The same decision process described may be used for this task. No matter which way it is handled, the process and the decision itself should be carefully documented.

### 3.5.5 IDENTIFYING DECISION OUTCOMES

One of the things that distinguishes risk management from other management approaches and decision-making methodologies is its focus on uncertainty. When decisions are made with less than perfect information, it is important to ask, "Is the decision working?" The answer to this question may not be evident in the near term when uncertainty is great, probabilities of occurrence are small, or time frames are long. On the other hand, we may learn quickly if our solution is working or not.

To deal effectively with uncertainty at this level of the process, the risk manager needs to identify one or more desired outcomes of the risk management option so we can verify that the solution is working. These outcomes should relate back to the risk management objectives. We want to be able to measure the impact of our risk decision(s) on public health, the company's bottom line, ecosystems, economic activity, or other appropriate outcomes. To do this we need outcomes that are measurable in principle. In some cases, the outcome may never, in fact, be measured, but if there is any question about the effectiveness of the RMO, it could be measured. There is no effective way to discern RMOs that work from those that do not without a performance measure.



### **DECISION MAKING FOR OPPORTUNITY RISKS**

The concepts of acceptable and tolerable risk differ between pure and opportunity risks. When we consider these terms from the perspective of an opportunity risk, an acceptable risk is one with a negligible probability of a negative outcome or with positive consequences so large that it offsets the chance of a negative outcome. Alternatively, the negative consequences may be so slight that individuals or groups in society are willing to take or be subjected to the risk. Investing in a project that has zero chance of negative net environmental benefits might be an acceptable risk.

A tolerable opportunity risk is one that is not acceptable. Risk taking is essentially different from risk avoiding. Risk taking decisions are conscious decisions to expose oneself to a risk that could have otherwise been avoided. Consequently, managing uncertainty prior to decision making or during evolutionary decision making is a significant risk management strategy for opportunity risks.

### **WHO OWNS THE RISK?**

Although we have spoken of risk managers as if they are all members of the same organization, that is rarely the case for decision making in the public sector. The success of an RMO may depend on many different people managing their piece of the risk.

A flood risk management (FRM) decision, for example, may require approval by and funding from Congress and the president. The U.S. Army Corps of Engineers must diligently construct all FRM structures approved by Congress. The county government may be expected to manage land use in flood hazard zones as part of the plan. State government may be responsible for operating and maintaining the FRM structures and individual residents of the flood plain may be expected to obtain flood insurance and obey evacuation orders.

A food safety risk analysis decision may involve producers, processors, wholesalers, retailers, and even consumers in the management of a risk.

Once a plan has been selected, the number of risk managers may increase markedly. They, of course, will not all have the full range of responsibilities described in this chapter.

### **3.5.6 IMPLEMENTING THE DECISION**

Implementing an RMO means acting on the decision that was made. It requires risk managers to identify and mobilize resources necessary to actualize the RMO. Implementing a decision will very often expand the definition of who is a risk manager.

Implementation may require the cooperation of many people outside the relatively small circle of people who have worked on a risk management issue. The details of the RMO must often be implemented by a great many people. A plan to reduce



traffic accidents may involve highway engineers, automobile manufacturers, drivers, and others. Reducing the number of illnesses from *Salmonella enteritidis* in shell eggs will involve farmers, food processors, transportation companies, retailers, and consumers. Many parties can own a piece of the responsibility for implementing risk management options. The specific manner of implementation will, of course, vary markedly with the nature of the risk problem and its solution.

What can we do to ensure that the various risk managers will cooperate and implement the chosen risk management strategy? This commitment is best achieved throughout the risk management process. Best practice calls for an explicit public involvement plan as part of the risk communication process for gaining commitment to the RMO. Stakeholders and the public can be expected to have an interest in the risk management decision. At a minimum, they need to know what the decision is, how it will affect them, and what their implementation responsibilities are. Most stakeholders will want to know how the decision was made and especially how trade-offs of interest to them were resolved. Risk managers must see that this communication takes place in a timely and effective manner.

### 3.6 RISK MONITORING

Good RMOs can fail through faulty implementation or unravel because of false assumptions. The most brilliant strategy can be undermined if communication breaks down. Risk analysis is an evidence-based process. What is the evidence our RMO is working? If we were charged in a court room with successfully managing the risk, would there be enough evidence to convict us?

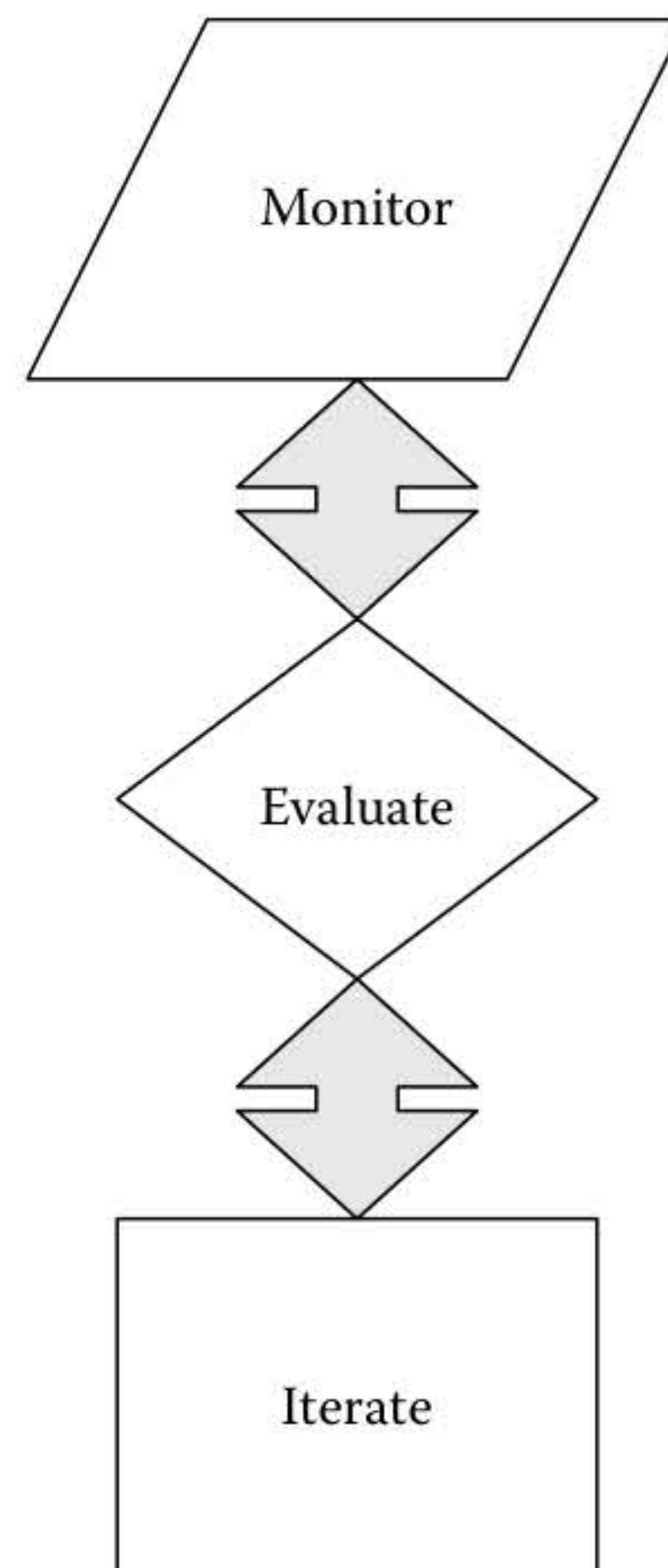
How do we know our solution works? Hubbard (2009) suggests that if we cannot answer this question, the most important thing a risk manager can do is find a way to answer it and then adopt an RMO that does work if the one currently in place does not. [Figure 3.11](#) shows the steps comprising the last risk management task: monitoring, evaluating, and iterating.

#### 3.6.1 MONITORING

It is important to provide feedback to the organization and its stakeholders on how well they are achieving their objectives. Risk managers are responsible for monitoring the outcomes of their decisions to see if they are working. There are actually three distinct things that may be monitored in any given situation. These are decision information, decision implementation, and decision outcomes.

Some risk management decisions may not yield immediately observable outcomes. Actions taken now to change conditions in the distant future are not observable, for example, measures taken to ameliorate effects of future sea level change. Some risk problems are so uncertain that the risks themselves may be considered speculative. It is difficult to observe the reduction of risks of rare events. In these kinds of situations, it may be important to monitor information to see if data gaps are being filled. Were the underlying assumptions of the risk assessment valid? Is the risk assessment consistent with the external data? If not, are the inconsistencies known and justified? As uncertainty is reduced, a new iteration of all or part of the risk management process





**FIGURE 3.11** Risk monitoring steps.

may be warranted. A new risk assessment, for example, may lead to better solutions in those instances where it is not yet possible to observe the effects of the RMO.

Monitoring actual implementation of the RMO is likely to be important in the near term once an organization decides to implement a specific measure. Are people doing what they are supposed to be doing? Audits can answer these questions for processes under the direct control of an organization, but when implementation requires large groups of stakeholders or the public to take or avoid certain activities, other methods of monitoring will be required. If everyone is doing what they need to do to get the RMO to work, then it is time to start monitoring outcomes.

A good risk management process will identify the outcomes to monitor in order to judge the success of an RMO. Monitoring means to watch, keep track of, or check for a special purpose. In this instance, that purpose is to determine if the desired risk reductions and other outcomes of an RMO are being achieved. In other words, “Are we meeting our risk management objectives?”

Decision makers do not always ask, “What measurable effect has our risk management option had?” The monitoring part of the risk management activity requires the risk manager to do that and to consider:

- What will we measure?
- How often will we measure?
- For how long will measurements be taken?
- Who will measure?
- What will they do with the measurements?
- Who will decide if the results are good, bad, or indifferent?



- How much will measurement cost?
- Who will pay?

It may not be necessary to begin to make these measurements immediately, but the desired outcomes (see Section 3.3.2.2) need to be identified before the RMO is implemented. Risk managers need to articulate for themselves and others what success looks like and how it will or could be measured. All of this should be tied directly to the risk management objectives so all can see how well they are being achieved and to allow for corrective action if necessary.

### 3.6.2 EVALUATION AND ITERATION

Once the monitoring information is gathered, it must be evaluated. This process should compare results to the original objectives to decide whether the RMO is successful. This means looking at the monitored outcomes data and judging them as satisfactory or not. One way to do this is to compare them with risk management expectations based on the risk assessment and other data. Are the desired risk reductions being achieved? Have you attained the potential benefits from your opportunities? An alternative evaluation can mean contrasting your results with what you believe is possible from other actions. Are these the best possible results? This evaluation is part of the risk manager's postimplementation responsibility.

If the evaluation step produces unsatisfactory results, the risk management decision should be modified. That modification most often will take the form of a new iteration of some or all of the risk management process. It could mean beginning again from the problem identification task, or revising and updating the risk assessment, or formulating new RMOs, or modifying the decision or its implementation strategy. The public and stakeholders should be kept informed of any and all postimplementation findings and changes in the risk management option.

Hubbard (2009) discusses four potential objective evaluations of risk management. The first is statistical inference based on a large sample. This can be a difficult way to establish the effectiveness of an option. For example, if the RMO is intended to reduce the risk of rare events, it could take a very long time indeed to compile a sample sufficient for drawing conclusions. The ability to perform risk management experiments is even more rare. Comparing results of experiments to establish the best measures is virtually unheard of in most risk management arenas. Opportunities to evaluate through statistical inference are limited by data.

Second, one can seek direct evidence of cause-and-effect relationships between our RMOs and lower risk. This approach is reasonably common in certain applications. For example, we have repeated evidence of public works projects producing the desired effects as well as of safety devices functioning as designed. Each time airport security catches a hazard at check-in we have evidence. When a seat belt restrains a passenger, there is a clear cause-and-effect relationship.

A third method is component testing of risk management options. This method looks at the gears of risk management rather than at the entire machine. Sometimes it is possible to examine how components of the RMO have fared under controlled experiments or prior experience even if we cannot evaluate the RMO as a whole. Thus,



if a pasteurization step in a food process achieves the desired log reduction in pathogens, we can have some confidence in the RMO that includes such a step.

A check of completeness is Hubbard's fourth suggestion. This technique does not measure the validity of a particular risk management method. Instead, it tries to address the question of whether the RMO is addressing a reasonably complete list of risks or risk components. You cannot manage a risk that no one has identified. Hubbard counsels risk managers to consider any list of considered risks to be incomplete.

To better ensure completeness, four perspectives should be considered: internal completeness, external completeness, historical completeness, and combinatorial completeness. Internal completeness requires the entire organization to be involved in risk identification. External completeness involves all stakeholders in identifying risks. Historical completeness considers more than recent history. It goes back as far as possible to consider potential situations of risk. Finally, the risk manager should consider combinations of events to help explore the unknown unknowns of risk.

### 3.7 RISK COMMUNICATION

Risk communication is a risk management responsibility that runs throughout the risk management model presented here. The risk manager need not conduct the risk communication but the risk manager is responsible for seeing that it gets done.

Risk managers must develop strategies for the internal and external communication required for successful risk management. Internal risk communication refers to essential risk communication that takes place within the risk analysis team, this is chiefly the communication between risk assessors and risk managers, although communication with risk communicators is, necessarily, a part of that process. The external communication process refers to communications between the risk analysis team and all those external to the team. Thus, external communications can involve members of the organization undertaking a specific risk management activity.

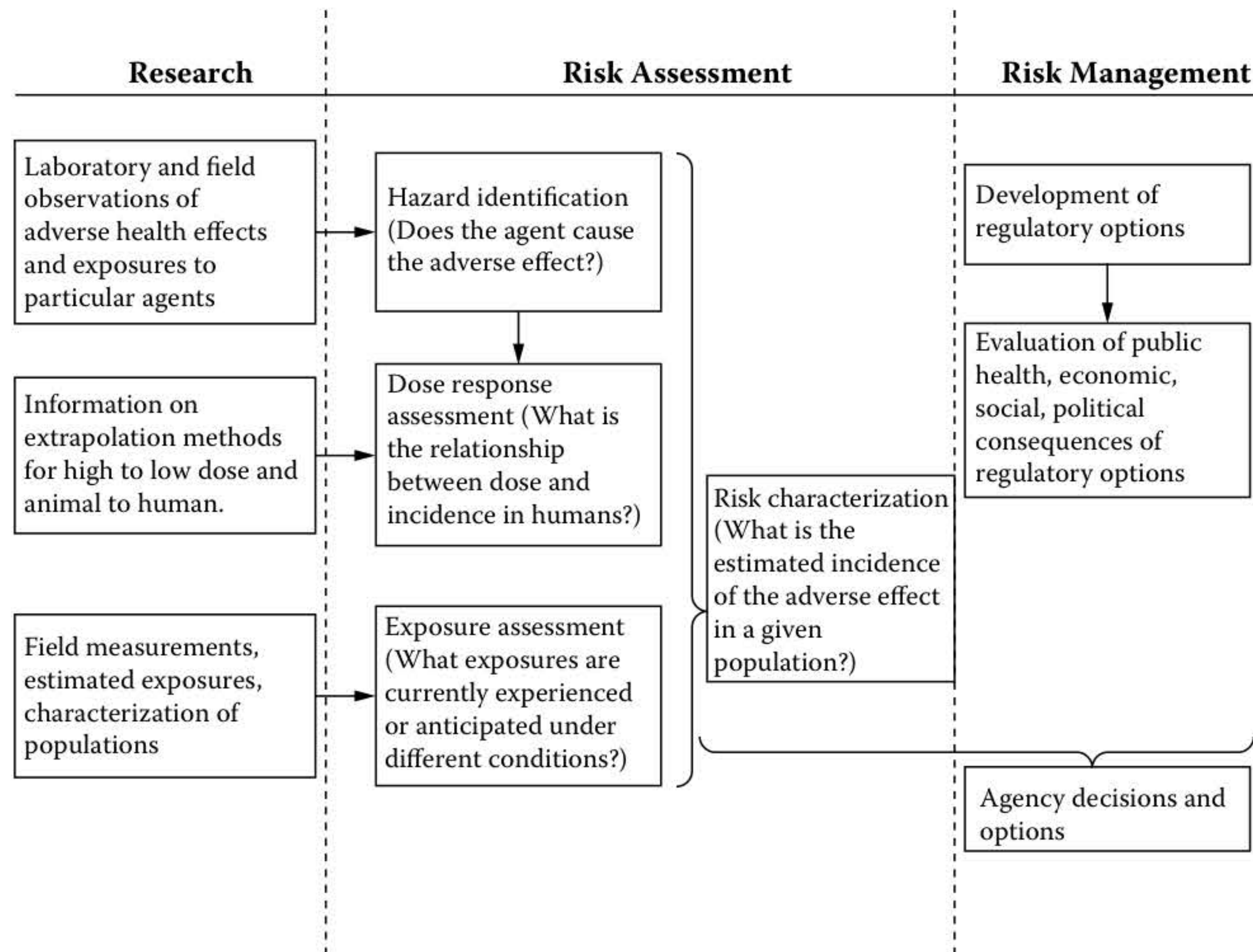
A transparent and open risk management process requires communication with all relevant stakeholders, and it is integral to good risk management decisions. This communication should include input and feedback opportunities for stakeholders as appropriate throughout the risk management activity.

It is important to make the communication process known to those with an interest in communicating. Communication must be timely. Risk managers, with the assistance of risk communicators and public involvement experts, must decide when and how to communicate. An open communication process shares what is being done to find answers to the important questions of risk managers and stakeholders. Providing public access to your data and models enhances both transparency and openness in a public-sector risk management process. Private-sector risk management will be much more circumspect. The nature of the risk communication task is addressed in [Chapter 5](#).

### 3.8 RISK MANAGEMENT MODELS

Very few people have actually been educated or formally trained to be risk managers. There are an infinite variety of ways to approach all or some subset of the tasks





**FIGURE 3.12** Elements of risk assessment and risk management. (National Research Council. 1983. Committee on the Institutional Means for Assessment of Risks to Public Health. *Risk assessment in the federal government: Managing the process*. Washington, DC: National Academies Press.)

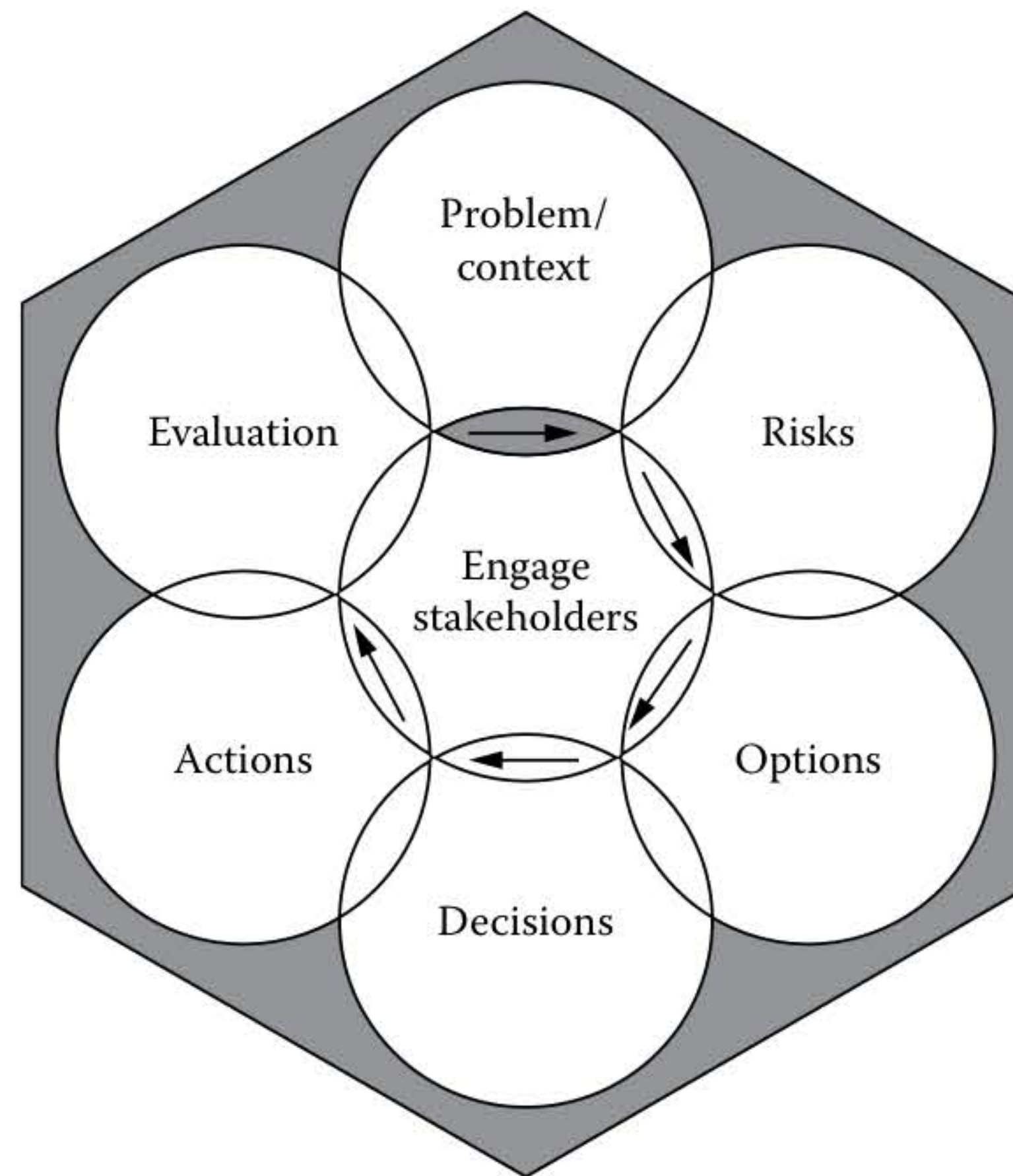
described in this chapter. It is helpful to have mental models that inform people about how an organization handles the risk management task. In the world of risk management, there are a few relatively generic models and many more organization- or application-specific models.

One of the earliest models of risk management, shown in Figure 3.12, comes from the “Red Book” (NRC 1983). In the early days of risk analysis, risk assessment was the centerpiece of the risk analysis process. Figure 3.12 shows that risk assessment is supported by research. Risk management in a government regulatory context is rather crudely depicted as a matter of formulating and choosing the regulatory option to use to respond to the assessed risks.

It is not much of a stretch to suggest that in the early days of risk analysis the general recognition of the existence of a risk initiated the conduct of a risk assessment. Risk management was more of a reaction to the risk assessment than the proactive, directive, and foundational step it is becoming today.

One of the first more evolved generic risk management models offered in the United States was developed by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997). It is shown in Figure 3.13. It begins with defining the problem and decision context and proceeds through a series of seven mostly distinct steps in an iterative fashion.





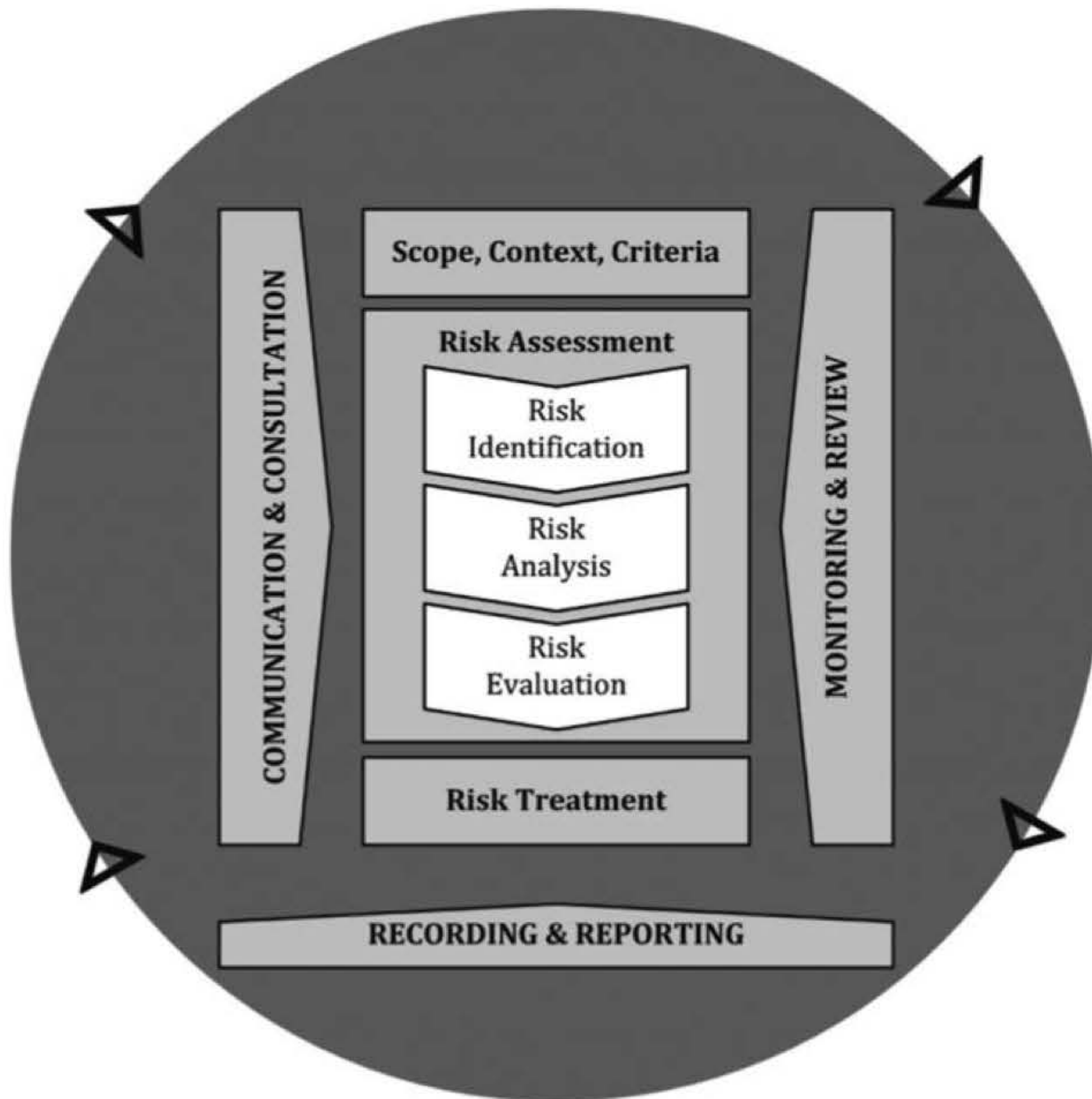
**FIGURE 3.13** Risk management framework of the Presidential/Congressional Commission on Risk Assessment and Risk Management.

Once the problem is defined, risks are identified and assessed, RMOs are formulated, and the best option is chosen in the decisions step. Implementation occurs in a series of actions, and the success of the RMO is subsequently evaluated. This can lead to another iteration of the risk management process. At the center of the process is stakeholder involvement.

One of the more widely applied risk management models was developed by the International Organization for Standardization (ISO), ISO 31000, “*Risk Management—Principles and Guidelines*” (ISO, 2009). The basic model is shown in [Figure 3.14](#). It is not specific to any industry or sector, and it can be applied to any type of risk, whatever its nature, whether it has positive or negative consequences. The model shown is quite consistent with the content of this chapter. The ISO risk management model has been updated and is revisited in [Chapter 6](#). Be forewarned that ISO defines many terms rather differently but at its heart is consistent with the process described in this chapter.

The ISO model has five steps and two ongoing processes as well as documentation, as seen in [Figure 3.14](#). It begins by establishing the decision context. This is followed by three steps that comprise the risk assessment process. Risks are identified and then qualitatively or quantitatively described in an analytical step (not to be confused with the overall risk analysis process) that produces information that enables risk evaluation. Risk treatment involves selecting one or more options for modifying risks and then implementing those options. Communication and consultation among managers and assessors as well as with external stakeholders takes place throughout the process. Monitoring and review embodies the iterative





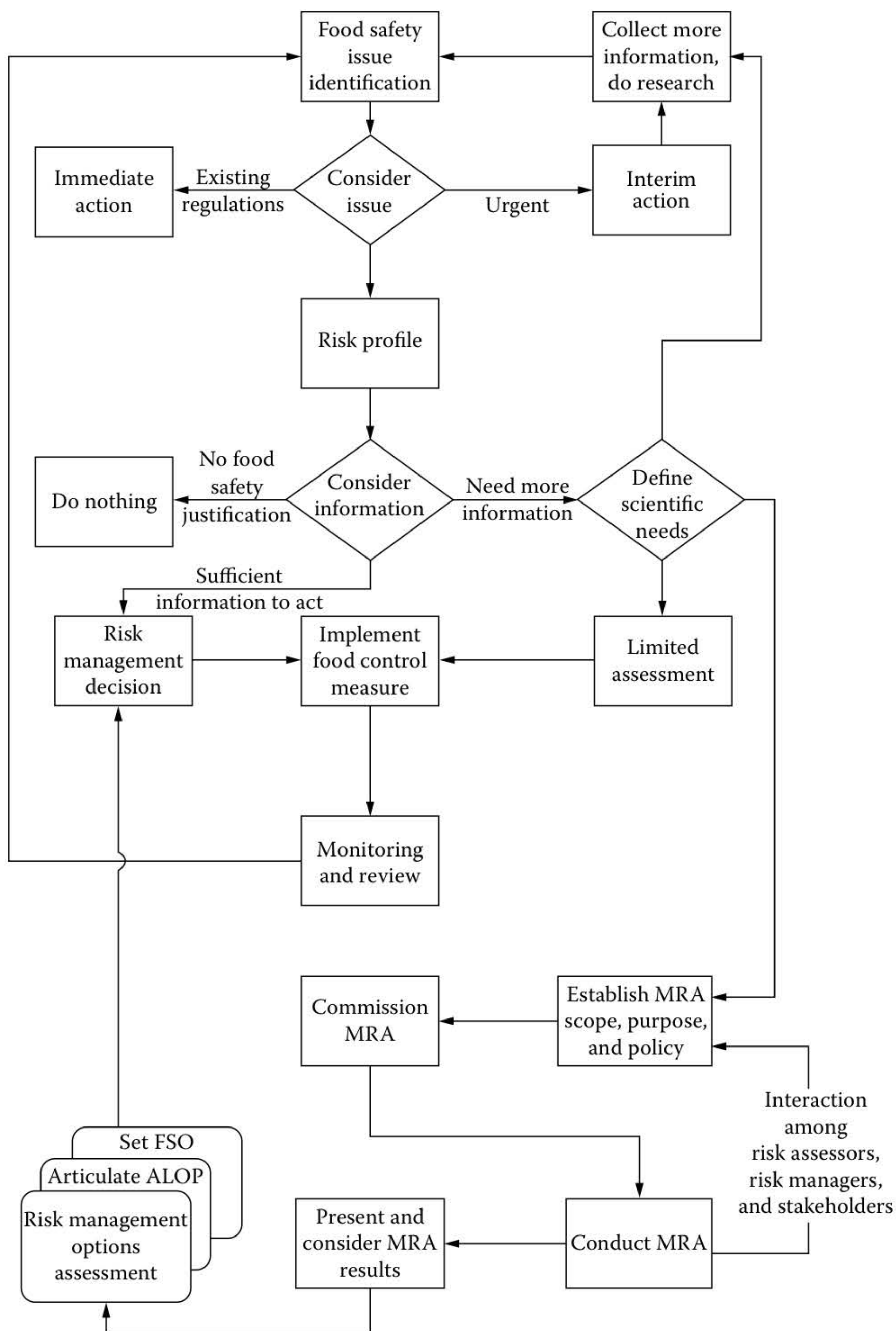
**FIGURE 3.14** International Organization for Standardization risk management framework.

nature of this risk management process as well as the kinds of tasks discussed in the body of this chapter.

In addition to these generic models, there are infinite varieties of application/organization-specific risk management models. One such model is presented in [Figure 3.15](#) as an example. This model is a microbiological risk management model (FAO 2003) to be applied to food safety problems. The details of this model are less important than the greater point that there is no one right way to do risk management. There are generic models that can be adapted for specific use; the model presented in this chapter and the ISO 31000 model are good examples. In addition, there are any number of organization-/industry-/application-specific models. The best of all of these embody most if not all of the tasks described previously in this chapter.

What is most important for any organization that seeks to do risk analysis is to develop its own risk management model or adapt and adopt one of the existing models. Risk management is a process. People must know and use the process; that means the organization must have one!





**FIGURE 3.15** Microbiological risk management model. (Food and Agricultural Organization. 2003. United Nations. *Guidelines for microbiological risk management*. Orlando, FL: Codex Committee on Food Hygiene.)



### 3.9 SUMMARY AND LOOK FORWARD

To do successful risk analysis you must have a risk management process. Then you must spend time working your process. Risk management begins and ends the risk analysis process. The risk manager's job may be described by the responsibilities they have in identifying risk, estimating risk, evaluating risk, controlling risk, and monitoring risk. You have to spend time on each of these activities to do good risk management.

Ultimately, the risk manager's job is to make effective and practical decisions under conditions of uncertainty. Establishing a process that ensures that the best available evidence is gathered, analyzed, and considered is the risk manager's responsibility. Carefully considering the instrumental uncertainties encountered in a risk management activity and seeing that their potential effects are carefully communicated to all interested parties is a primary responsibility of the risk manager.

The next chapter continues to unpack and explain the components of the risk analysis process. The practice of risk assessment is endlessly varied because of the broad and growing number of applications of the risk analysis paradigm. Risk assessment is where the initial focus of the evolving risk analysis paradigm was concentrated. In fact, there are many practitioners who would argue vociferously that risk assessment is still the heart of risk analysis. Consistent with the aim of this text, the common elements of many of these risk assessment models are identified and presented.

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