4 Risk Assessment

4.1 INTRODUCTION

Risk assessment pursues truth. Some risk assessments require science to discern that truth. In private-sector organizations, many risk assessments simply require sound evidence to know the truth. The absolute truth is usually opaque, because of uncertainty. Good risk assessment tells the truth about what we know and what we do not know. It is the science-based component of risk analysis that provides the evidence for decision makers. It answers the risk manager's questions about the risks. It provides the objective information needed for decision making, including a characterization of the instrumental uncertainty that could influence the decision or its outcome. An assessment is done to gain an understanding of the risk(s) and to measure and describe them to the fullest extent possible. A good risk assessment meets the information needs of risk managers for decision making. It provides an objective, unbiased treatment of the available evidence in well-organized and easy to understand documentation that clearly links the evidence to its conclusions. It also describes and addresses uncertainty in intentional ways.

Risk assessment is based on orderly reasoning. It is a set of logical, systematic, evidence-based analytical activities designed to provide risk managers with the best possible identification and description of the risk(s) associated with the decision problem. Evidence can be considered to include anything that helps assessors and managers discern the truth about matters of concern to them. Risk assessment is a methodical process with specific steps that provide for a thorough and consistent approach to the assessment of risks. It meets the manager's specific decision-making needs for timing, quality, and comprehensiveness of evidence. It also provides a thorough appreciation for the uncertainties that attend those risks. Because it includes the best available scientific knowledge, it is science-based.

SCALABLE RISK ASSESSMENT

In practice, you can find that there are risk assessments that warrant the complete treatment described in this chapter and there are risk assessments that require little more than the application of a risk assessment tool. Risk assessment can take months or years and a team of people with a very large budget or it may take one person with a risk matrix an hour or so, as well as everything between these two extremes.

This chapter describes a process that is suitable for any risk assessment effort, although it is presented as if for a substantial analytical effort. The process is, of course, perfectly scalable and its steps are as suitable for that multi-year effort as it is for the one-hour effort.

This chapter begins by considering what makes a good risk assessment. This is followed by a few definitions. Risk assessment models and techniques vary widely from one application to the next. The common elements of these have been distilled into a generic set of risk assessment activities, the description of which comprises the bulk of the chapter. Several specific risk assessment models are presented to illustrate the manner in which some communities of practice have formalized the assessment process. The chapter concludes with a brief description of the differences between qualitative and quantitative risk assessment.

4.2 WHAT MAKES A GOOD RISK ASSESSMENT?

During the 1990s, I offered a week-long course in risk assessment through the U.S. Department of Agriculture Graduate School. On Friday afternoon I always had a panel of practitioners come in and speak about what makes a good risk assessment. I sat in the back of the room and took notes. Those notes are summarized below in 14 aspects of a good risk assessment process (see text box).

A good risk assessment gets the questions right, then answers them carefully. Good risk assessment begins with the questions risk managers would like to have answered in order to manage the risk. These are to be answered by the risk assessment. In best practice, risk assessors will understand the entire decision context and help ensure that risk managers get the questions right. Good risk assessment answers the questions clearly and concisely.

Risk assessment is usually a team sport. Evidence-based analysis requires subject matter experts. It is unusual, but certainly not unheard of, for a single person to be able to complete a risk assessment. As risk analysis grows in acceptance, the number of routine risk assessment applications likewise increases. The more complex and unique risk assessments are never completed by a single person. Good teams are at least multidisciplinary. Better teams are interdisciplinary. The best teams are transdisciplinary.

WHAT MAKES A GOOD RISK ASSESSMENT?

Here are the 14 aspects of a good risk assessment described in this section:

Questions	Sensitivity
Team	Relevant Risks
Magnitude of Effort	Qualities
Point of View	Results
Science/Assumption	Evaluation
Data	Education
Uncertainty	Documentation

Multidisciplinary teams ensure that the needed expertise is available. Experts on these teams tend to function as experts in isolation of one another's disciplines. The knowledge tends to be integrated by one or a few individuals. This stands in contrast

to the interdisciplinary team, where all the experts integrate their knowledge with that of others. Engineers understand something about economics, and economists understand a little engineering. Biologists know a little about what the statistician is doing, and the statistician knows some biology. The team itself is integrating the knowledge of its member experts. An interdisciplinary team works more efficiently and effectively than a multidisciplinary team. A transdisciplinary team dissolves the boundaries among disciplines and moves beyond integration to assimilation of perspectives. In the process they are often able to construct knowledge and understanding that transcends the individual disciplines. Transdisciplinary teams are preferred, but they are still rare.

The best teams spend time together working on substantive issues of common interest. Good assessment teams are collaborative and effective. Roles and responsibilities are well defined and conscientiously executed. The team answers the risk manager's questions.

The magnitude of a good assessment effort is commensurate with the resources available and in proportion to the seriousness of the problem. The effort should reflect the level of risk. Risk analysis in general and risk assessment in particular are perfectly scalable processes. A good risk assessment process can be completed in an hour if that is all the time you have or in a couple of years if that is what is warranted—the attendant uncertainty will vary markedly between these situations. The assessment process does not have to take months or years and millions of dollars, but there may be a lot of uncertainty in a quick one.

The process itself is often as valuable as the result. The process provides a basis for trust as well as for information. The process aids the understanding of the problem and its solutions. The process has to be sufficient to allow for answers to the questions posed by risk managers.

A good risk assessment has no point of view. It yields the same answers to the same questions regardless of who finances or sponsors the assessment. Although a question from the risk managers may, appropriately, reflect a point of view, the answer never should. It is not the assessor's job to protect the children, to make a product look profitable, to punish or reward anyone. It is to provide objective evidence-based answers to the questions they have been asked.

On a related note, assessors should not pursue their own curiosity in a risk assessment. Nor should they ever pursue a desired answer to any question. An assessment should never be designed to provide analysis to support a predetermined answer. If risk managers know what they want to do, a risk assessment is not necessary. Not every decision requires a risk assessment. Those that do, begin with the questions that are objectively answered.

Good risk assessment separates what we know from what we do not know, and it focuses special attention on what we do not know. Risk assessment is not pure science. The existence of uncertainty often prevents it from being so, but good risk assessment gets the right science into the assessment and then it gets that science right. Science provides the basis for answering the risk manager's questions. Honesty about uncertainty provides the confidence bounds on those answers.

Good science, good data, good models, and the best available evidence are integral to good risk assessment. Assessors need to tie their analysis to the

evidence and to take care to ensure the validity of the data they use. It is both useful and important to know that not all data are quantitative. Likewise, data are not information. Skilled assessors are needed to extract the information value from data in ways that are useful and meaningful to risk managers. The answers to the risk manager's questions stand or fall on the quality of the information used to answer the questions.

It is the way that risk analysis handles the things we do not know that makes it such a useful and distinctive decision-making paradigm. In a good risk assessment, all assumptions are clearly identified for the benefit of other members of the assessment team, risk managers, and anyone else who will read or rely upon the results of the risk assessment. Risk assessors should not rely on their own default assumptions. If any default assumptions are to be used, they should be identified in the organization's risk assessment policy, prepared by risk managers.

There is uncertainty in every decision context. Risk assessors must recognize the uncertainty that exists. Moreover, they need to identify the instrumental uncertainties that influence the answers to questions, describe their significance for decision making and decision outcomes, and then address these uncertainties appropriately throughout the risk assessment. There has always been uncertainty in decision making. In the past, including the recent past, it has been commonplace to overlook or ignore the existence of uncertainty, often to the regret of those affected by decisions made this way. Admitting the things that one does not know when making a decision has often been perceived as a weakness. We like confident and bold decision makers. But we also like decisions that produce good outcomes, and the two are not always compatible. Uncertainty analysis is a strength of good risk assessment, not a weakness. Good risk assessment addresses knowledge uncertainty and natural variability in the risk assessment inputs. Good risk management addresses the variation, that is, the remaining uncertainty, in risk assessment outputs.

ASSUMPTIONS

No risk assessment can be completed unless the evidence is supplemented with assumptions. Explicit assumptions are those that assessors consciously make. In principle they can be readily documented.

Implicit assumptions are those that escape the conscious awareness of the assessors. They may be based on the culture of the organization, the beliefs of the assessors, the basic assumptions, principles and theories of the different disciplines employed, and so on. They are rarely documented. An independent review of a risk assessment by a multidisciplinary review panel can often be effective in picking up implicit assumptions, because the implicit assumptions of one discipline or person often conflict with those of another discipline or person and, thus, stand out.

All significant assumptions, whether explicit or implicit, need to be conveyed to the risk managers and other users of the assessment.

Sensitivity analysis should be a part of every risk assessment, qualitative or quantitative. Testing the sensitivity of assessment results, including the answers to the risk manager's questions, to changes in the assumptions assessors made to deal with the uncertainties they encountered is a minimum requirement for every assessment. Explaining how this uncertainty could affect decision making or the outcomes of decisions is the endgame for sensitivity analysis. The scenarios used to describe the risks we assess must reflect reality. That means they should be based on good science and field experience. Risk assessors need to understand how answers to the risk manager's questions might change if realizations of risk assessment inputs were to change due to their uncertainty.

The risk assessment should address all the relevant risks. Risk is everywhere. Zero risk is not an option for any of us. Risk assessment is different from safety analysis, although safety analysis is an integral part of some risk assessments. To distinguish risk assessment from safety analysis, we need to consider risk broadly and focus on the risks of interest. These may include:

- Existing risk
- Future risk
- Historical risk
- Risk reduction
- New risk
- Residual risk
- Transferred risk
- Transformed risk

It will not always be necessary to consider each of these kinds of risk but it is rarely adequate to consider only one of these kinds of risk. Good risk assessment considers both the explicit and implicit risks relevant to the questions posed by risk managers.

Good risk assessments share some qualities in common. First, they are unbiased and objective. They tell the truth about what is known and not known about the risks. They are as transparent and as simple as possible but no simpler. Practicality, logic, comprehensiveness, conciseness, clarity, and consistency are additional qualities desired in a risk assessment. Of course, a risk assessment must be relevant. To be relevant it must answer the questions risk managers have asked.

Risk assessments may produce more estimates and insights than scientific facts. The assessment results provide information to risk managers; they do not always produce the truth and they never produce decisions. Risk managers make decisions. The best assessments evaluate their own assumptions and judgments and convey that information to risk managers and other interested parties often in the form of confidence or uncertainty ratings. A good process makes the assessment open to evaluation. It is often wise to submit a controversial or important risk assessment to an independent evaluation or peer review.

Good risk assessments can have educational value. They often identify the limits of our knowledge and in so doing guide future research. They can help direct resources to narrowing information gaps. They help us learn about the problems, our objectives, and the right questions to ask. Completed risk assessments may be conducive to learning about similar or related risks.

There may be more than one audience for the risk assessment. Each audience is likely to have different information needs and they may each require separate documentation. This makes documentation an important part of the risk assessment process. Effective documentation tells a good story well. It is explained in simple terms and is readable by the intended audience. A good document is clear and spells important details out in terms the audience can understand. Scientific details are often most appropriately presented in technical appendices. Most important, a good risk assessment lays out the answers to the risk manager's questions clearly, well, and simply.

4.3 RISK ASSESSMENT DEFINED

At its simplest, risk assessment is estimating the risks associated with different hazards, opportunities for gain, or risk management options. Many definitions of risk assessment simply identify the steps that comprise the assessment process for that application. No one definition is going to meet the needs of the many and disparate uses of risk assessment. Nonetheless, it can be informative to consider a few formal definitions.

RISK ASSESSMENT LANGUAGE IS ALSO MESSY

The World Organization for Animal Health (OIE) defines risk assessment as follows:

The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country.

It has four steps:

1. Release assessment
2. Exposure assessment
3. Consequence assessment
4. Risk estimation

The International Plant Protection Convention of the United Nations defines risk assessment as:

"Determination of whether a pest is a quarantine pest and evaluation of its introduction potential."

ISO Guide 73:2009, definition 3.4.1 defines risk assessment as the overall process of risk identification, risk analysis and risk evaluation.

There are no generally agreed upon definitions for risk assessment. Fortunately, the ability to develop useful and serviceable definitions for specific organizations and applications has rendered the need for a single generic definition moot. Feel free to adopt, adapt, or invent your own definition if it helps you describe the risk(s) of interest to you.

The seminal definition may be found in *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983, p. 19). This book, known widely as the "Red Book," for its cover, represents the first formal attempt to provide a description of the risk assessment process. The risks of primary interest at the time were chemical risks found in the human environment. Risk assessment was initially defined as follows: "Risk assessment can be divided into four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization."

The steps are described by the National Research Council (NRC) as follows:

- *Hazard identification*: the determination of whether a particular chemical is or is not causally linked to particular health effects
- *Dose-response assessment*: the determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question
- *Exposure assessment*: the determination of the extent of human exposure before or after application of regulatory controls
- *Risk characterization*: the description of the nature and often the magnitude of human risk, including attendant uncertainty

RISK ASSESSMENT

When asked to name the riskiest things they do, most people will quickly identify driving. A simple risk assessment process can be demonstrated by asking the four questions used to define risk assessment in Chapter 1.

What can go wrong? One could have an accident.

How can it happen? The driver could be impaired, road or weather conditions could be hazardous, the car could be poorly maintained.

What are the consequences? Property damage, injury, fatalities, or perhaps only delay and annoyance could result from an accident.

How likely is it? Perhaps knowing yourself you might say, not very likely.

That is a risk assessment process. Is it good enough to run an insurance company or to design highways? Of course not! However, it is perfectly adequate to demonstrate the idea of a scalable and systematic process. Given more time, resources, and importance, all of the answers could be expanded and quantified.

STEM

Cox (2002) says a risk can be defined by answering the following four questions:

- What is the **source** of the risk?
- What or who is the **target** that is at risk?

- What is the adverse **effect** of concern that the source may cause in exposed targets?
- By what causal **mechanism** does the source increase the probability of the effect in exposed targets?

These definitions have been and continue to be the focal point for many definitions of risk assessment. The *Codex Alimentarius*, for example, defined risk assessment for food safety purposes in 2004 as follows: "Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization" (FAO/WHO, 2004, p. 45). The roots of the original definition are clearly evident in this one, which has simply broadened the notion of using a dose-response assessment to characterize the consequences of exposure to a hazard.

The NRC definition as broadened by the *Codex* has a lot of appeal for risk assessors. It begins by identifying the hazard, which is the thing or activity that can cause harm. The hazard characterization step describes the nature of that harm and the conditions required to cause it. The exposure assessment describes the manner in which people or other assets of value can become exposed to the hazard under conditions that will cause harm. The last step, risk characterization, pulls together the information in the three preceding steps to describe the probability that the risk will occur as well as the severity of its consequences.

The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997a,b) defined risk assessment more generally. It said that risk assessment is the systematic, scientific characterization of potential adverse effects of human or ecological exposures to hazardous agents or activities. It is performed by considering the types of hazards, the extent of exposure to the hazards, and information about the relationship between exposures and responses, including variation in susceptibility. Adverse effects or responses could result from exposures to chemicals, microorganisms, radiation, or natural events. This definition did not catch on with federal agencies in the United States because it did not meet the widely varying needs of the agencies using risk assessment.

ISO 31000:2009 *Risk Management--Principles and Guidelines* (ISO, 2009) defines risk assessment as the overall process of risk identification, risk analysis, and risk evaluation. Beware the messy language of risk! Risk identification is the process of finding, recognizing, and describing risks. Risk analysis is a process to comprehend the nature of risk and to determine the level of risk. It is equivalent to risk assessment as described in this chapter. Risk evaluation is the process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable. The Society for Risk Analysis defines risk assessment as a systematic process to comprehend the nature of risk, express and evaluate risk, with the available knowledge.

For the general purposes of this book, risk assessment is defined as a systematic evidence-based process for describing (qualitatively or quantitatively) the nature, likelihood, and magnitude of risk associated with some substance, situation, action,

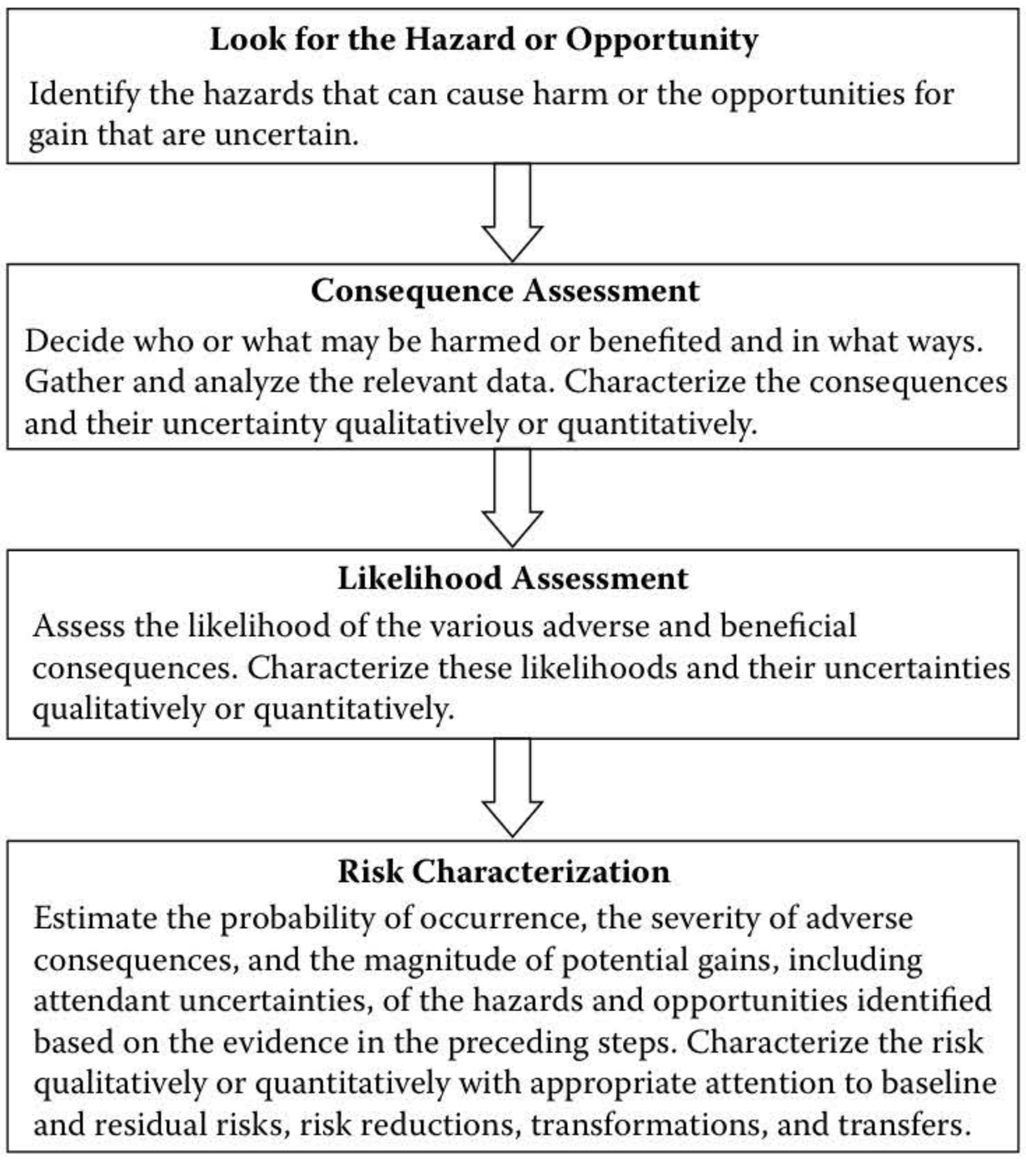

FIGURE 4.1 Four generic risk assessment components.

or event that includes consideration of relevant uncertainties. The generic assessment steps adopted for this book are shown in Figure 4.1.

Risk assessment is a continuously evolving process with a stable core that takes many forms, as evidenced by the previous definitions and the models that follow in this chapter. The core of risk assessment may best be described by the four informal questions introduced in Chapter 1:

- What can go wrong?
- How can it happen?
- What are the consequences?
- How likely is it to happen?

4.4 RISK ASSESSMENT ACTIVITIES

The great variety of risk assessment models, methods, and applications makes it difficult to speak about risk assessment in a way with which all will agree. I describe the risk assessment component of risk analysis by breaking it down into eight generic risk assessment tasks that appear to varying extents in one form or another in all best-practice risk assessment. They are shown in Figure 4.2 and are addressed in the sections that follow.

The tasks, although presented in a linear fashion, are often accomplished in an iterative fashion. Some tasks may be initiated simultaneously, for example, the consequence and likelihood assessments may be done concurrently. It is less important that the tasks be accomplished in a rigid fashion than that all of the tasks get done at least once.

4.4.1 Understand the Questions

In case you had not picked up on the importance of questions from earlier in the chapter, risk assessors need to understand what information they are being asked to provide back to risk managers. Assessors are often involved in helping risk managers to identify the questions that need to be answered for risk managers to achieve their risk management objectives and solve their problems. Questions are just one common way of eliciting information that is needed for decision making. Questions need not literally be questions. Information needs can be expressed in any number of ways. Whether assessors are involved or not, obtaining a preliminary set of the questions to be answered by the risk assessment is the essential starting point for any risk assessment.

Assessors should review the questions with the managers to make sure they have a common understanding of the meaning of the questions and the information required to answer them. If the assessors know it is going to be impossible to answer some of the questions, they need to tell the risk managers this. A revised set of questions needs to be negotiated and approved by the managers. If important questions are missing, assessors should argue for their inclusion.

SOME REAL QUESTIONS

What is known about the dose-response relationship between consumption of *Vibrio parahaemolyticus* and illnesses?

What is the frequency and extent of pathogenic strains of *Vibrio parahaemolyticus* in shellfish waters and in oysters?

What environmental parameters (e.g., water temperature, salinity) can be used to predict the presence of *Vibrio parahaemolyticus* in oysters?

How do levels of *Vibrio parahaemolyticus* in oysters at harvest compare to levels at consumption?

What is the role of post-harvest handling on the level of *Vibrio parahaemolyticus* in oysters?

What reductions in risk can be anticipated with different potential intervention strategies?

Source: Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio parahaemolyticus in Raw Oysters (FDA, 2005).

Some organizations face recurring situations or they handle a specific kind of risky situation as a matter of routine. In these instances, the specific questions to be answered may be well known and long established. For example, the Animal Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture routinely

processes requests from countries that would like to export their plants and plant products to the United States. APHIS has developed a standardized risk assessment process that relies on a well-defined set of questions that is used for all such routine requests.

The U.S. Army Corps of Engineers routinely addresses flood problems across the country. No two of them are alike, but flood risk management investigations are similar enough that many of the information needs have become standardized. Estimating what the expected annual flood damages are with and without risk management measures in place are universal questions that have been standardized in guidance documents and practice.

The food-additive safety assessment process has a well-established procedure for assessing health risks of chemicals added to food. It begins by undertaking toxicity studies of the substance. These studies are used to determine the "No Observed Adverse Effect Level" (NOAEL). A safety or uncertainty factor is used to extrapolate the NOAEL results from animals to humans. Dividing the NOAEL by the safety factor yields an Acceptable Daily Intake (ADI). This is the maximum amount the average human can consume daily for a lifetime with no adverse health effect. Simultaneous efforts to calculate the Estimated Daily Intake (EDI) of the substance are undertaken, and the two are compared via the ratio, EDI/ADI. Values greater than 1 require risk management. These data input requirements are well established.

SELECTED SOURCES OF SCIENTIFIC INFORMATION FOR RISK ASSESSMENTS

- Published scientific studies
- Professional literature
- Specific research studies designed to fill data gaps
- Administrative data and internal documents
- Gray literature—unpublished studies and surveys carried out by academia, government, industry, and nongovernmental agencies
- National and other monitoring data
- National human health surveillance and laboratory diagnostic data
- Disease outbreak investigations
- National, published, and proprietary surveys, inventories, and the like
- Expert panels to elicit expert opinion where specific data sets are not available
- Risk assessments carried out by others
- International databases
- International risk assessments

Thus, the risk manager's data needs may already be well established for some risk assessments. These will usually be available in official policy, guidance, or common practice. In other unique instances, risk managers will have to carefully articulate each of their data needs. The majority of risk assessments may well fall between these two extremes. Regardless of the individual circumstances of an assessment, the risk

manager's questions should be written down and understood by all. These questions guide the risk assessment.

4.4.2 Identify the Source of the Risk

Data collection and analysis begin in earnest when risk assessors seek to identify, understand, and describe the source of the harm that could occur or the gain that may be realized. The source of the risk—the hazards that can cause harm or the opportunities for gain that are uncertain—may already have been identified, as the decision context was established by the managers, with or without the assistance of the assessors, especially if a risk profile was prepared first. It is usual for assessors to participate in the preparation of a risk profile.

In many risk assessment models, this step is called "hazard identification." For Environmental Protection Agency (EPA) Superfund risks, this is the process of determining whether exposure to a chemical agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defects) and whether the adverse health effect is likely to occur in humans. For food safety concerns, it may mean identifying a pathogen-commodity pair that is of concern. For engineering projects, it may mean describing an earthquake or coastal storm risk, or it could be determining the demand on a structural component relative to its capacity. For APHIS, it may include identifying a pest of potential quarantine concern. For a pharmaceutical firm, it may be impurities or irregularities in the production of a drug. It could also mean identifying the potential gains from an investment in tourism or the gain associated with opening a new store or launching a new product line. In enterprise risk management it could be anything that threatens a firm's ability to meet its strategic objectives.

TWO CONSEQUENCE CAVEATS

Managers and assessors need to remain vigilant against imprecise language. It is easy to ask: what is the risk associated with eating oysters contaminated with pathogenic Vibrio parahaemolyticus? But what are the consequences of concern to risk managers? Is it annual deaths, hospitalizations, illnesses, or exposures? Should they be segregated by age, gender, ethnicity, or other factors? Do we want estimates of the probability of death and illness? If so, should they be per exposure or annually? Or are other measures like loss of life expectancy, working days lost, and quality adjusted life years appropriate?

Managers and assessors also need to think broadly about consequences. A narrow focus on consequences can cause managers to overlook important impacts of both the risk and the RMOs. For example, if the assessment is motivated by public health consequences it is easy to overlook important impacts on trade, industry, and consumers.

The cure for these mistakes is found in a good risk management process and those "three pieces of paper" it produces.

Identifying the source of the risk is more than simply naming a hazard or opportunity. It includes understanding the background, context, and aspects of the hazard or opportunity relevant to the problem being addressed and communicating that to others. The extent of this process will vary from situation to situation. For example, identifying a food-borne pathogen may be very straightforward for well-known microbiological hazards yet far from fully developed for emerging or new microbiological hazards. Economic opportunities may need to be supported with market studies and cost details. Technological risks need to be explained in a narrative fashion that facilitates understanding by all interested parties. In other words, assessors must gather the evidence necessary to establish the existence of a hazard or opportunity.

The risk assessor should think comprehensively about risks. This means identifying all of the decision-relevant risks. It is all too easy to focus too narrowly and too quickly on a single risk when there may in fact be more than one. It also means considering all the relevant dimensions of a risk, including not only the existing risk, but residual, new, transformed, and transferred risks. Identifying the source of a risk is primarily a qualitative analysis. Importantly, hazard/opportunity identification is the point in the risk assessment where risk assessors begin to carefully identify and separate what we know about a risk from what we do not know.

4.4.3 Consequence Assessment

In this task, risk assessors characterize the nature of the harm caused by a hazard or the gain that is possible with an opportunity. Assessors identify who or what may be harmed or benefited and in what ways by the sources of risk identified in the previous task. This activity might be described as the cause-effect link in the risk assessment. What undesirable effects do the hazards have? What desirable effects might the opportunities offer? Risks affect human, animal, and plant life, public health, public safety, ecosystems, property, natural and cultural resources, human systems (political, legal, education, transportation, communication, and the like), business operations and bottom lines, infrastructure, economies, international trade and treaties, financial resources, and so on. Carefully identifying the consequences and linking them to the hazards and opportunities is an essential early step in any risk assessment. It also helps solidify the definition of the risk. This activity may be likened to the hazard characterization step of the Codex model.

The consequences of most importance should already be reflected in the "three pieces of paper" developed by risk managers before the risk assessment was initiated. In an iterative process, such as risk assessment, it is to be expected that, as uncertainty is reduced, some aspects of the assessment will become better understood. This may necessitate revising the initial assessment of relevant consequences.

Effectively managing a risk requires a broad understanding of the relevant losses, harm, consequences, and potential gains to all interested and affected parties (NRC, 1996). Consequences may be characterized qualitatively or quantitatively. No matter which type of characterization is used, it is essential to catalogue the significant uncertainties encountered in describing and linking the consequence to the source hazards and opportunities.

If the risk has not previously been carefully identified, it will be useful to identify the specific consequences of interest in the assessment before initiating the likelihood assessment. As noted earlier, it is important to answer the "likelihood of what?" question before investing much effort in assessing the likelihood. In ongoing programs with recurring types of risks the consequences may be well defined by policy and practice that enable the assessors to conduct a simultaneous likelihood assessment.

4.4.3.1 Dose-Response Relationships

The earliest risk assessments used dose-response relationships to characterize the consequences of human health risks. Dose-response relationships, often represented as curves, remain the primary health-consequence model used to characterize the adverse human health effects of chemicals, toxins, and microbes in the environment. There is extensive literature on these dose-response relationships that includes its own journal, *Dose-Response*. A discussion of consequence assessment is not complete without a brief mention of this often-used relationship.

Consider the conceptual representation of a dose-response curve shown in Figure 4.3, adapted from Covello and Merkhofer (1993), where they described the effect of a risk agent on a large population. First, notice that the dose of the risk agent increases from left to right on the horizontal axis. The response, on the vertical axis, is not specified. In practice, this axis may be the probability of illness or of some other adverse health effect, the number of excess tumors above those observed in a control group, for example, or virtually any adverse health effect. The metrics on the vertical axis are most often developed for a representative individual of the general population, the general population itself, or any subpopulation of interest.

Five different conceptual distinctions are made in the figure to aid the general understanding of the relationship. Let us illustrate these concepts using two different responses. The first is an unspecified set of variable adverse health effects

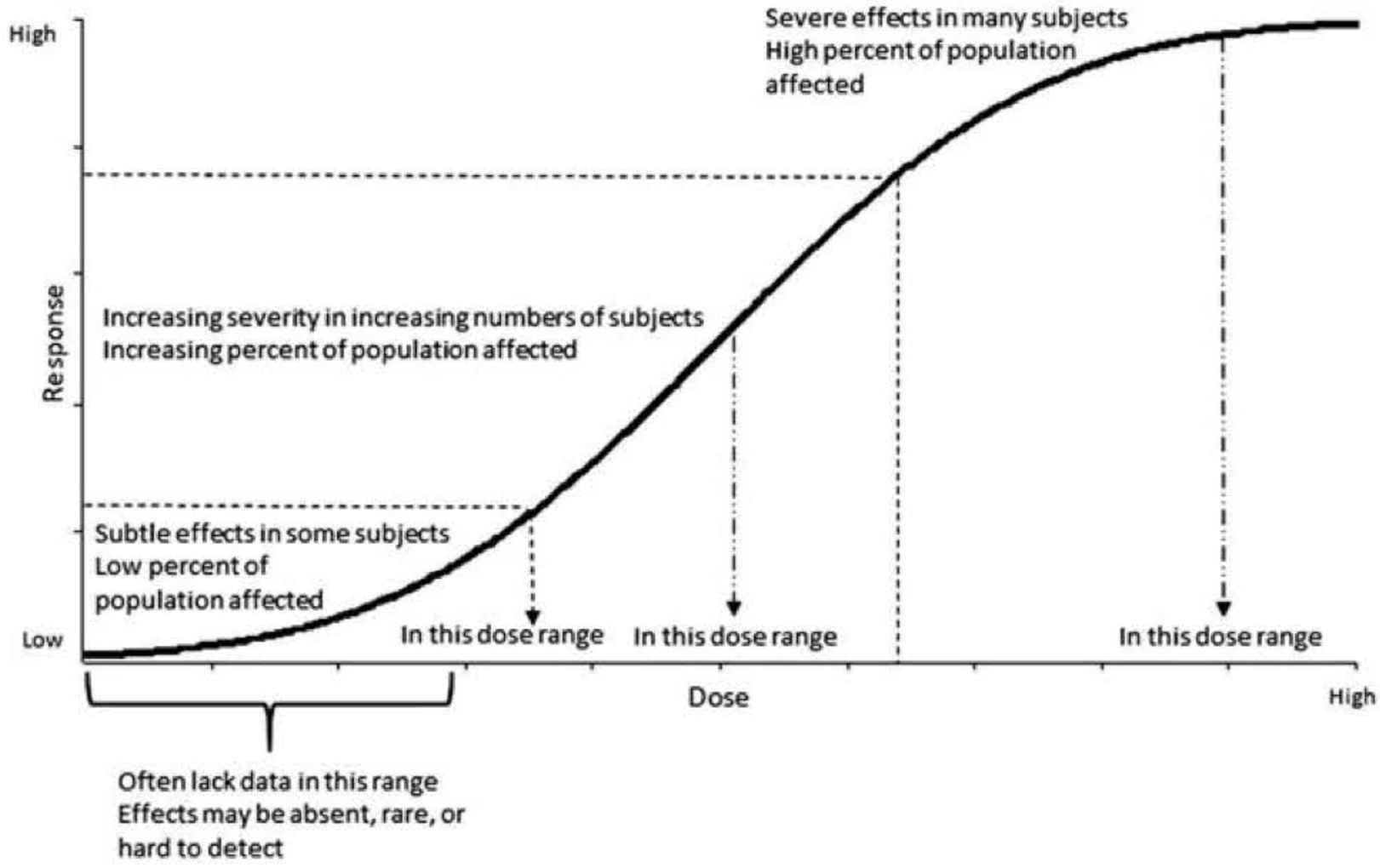

FIGURE 4.3 A stylized dose-response relationship.

encompassing such effects as excessive salivation, elevated blood pressure, infection, organ failure, and death. The second response is lifetime probability of cancer. First, at sufficiently low doses there may be significant uncertainty about the response. "No threshold" models assume there is no absolutely safe level of exposure. However, for many risk agents there may be no effects at very low doses regardless of the duration of the exposure. At this level of exposure when the response is, say, the probability of cancer for a representative member of the population, the shape of the curve in this range of doses may be highly uncertain.

At somewhat higher levels of exposure, subtle adverse health responses may be detected in some subjects. This might include low impact effects like excess salivation or using the probability of cancer, we would see a low but increasing probability.

As the dose increases more, we might see the beginning of some severe effects in some members of the population with a growing number of less severe effects. The cancer risk model simply has an increasing likelihood of cancer. In that fourth dose region, we would expect to see increasing numbers of severe health effects among members of the population. Both incidence and severity increase with these relatively high doses of the risk agent. If the dose increases high enough and lasts long enough, all members of the population are at risk of some adverse response. Similarly, the probability of cancer rises to higher levels. The final response range corresponding to the highest dose levels results in death or a probability of cancer approaching one.

This conceptual model is not to be taken literally. Response will not always be a continuum from no effects to death; the probability of cancer response presents one alternative. The doses themselves will vary as well. Chemical exposures, for example, may be measured in mg/kg/body weight daily for a lifetime. Microbial doses may be measured in the number of cells or colony-forming units per some amount of food.

4.4.4 Likelihood Assessment

Risk assessors analyze the manner in which the undesirable consequences of hazards or the desirable consequences of opportunities occur so they can characterize the likelihoods of the sequence of events that produce these outcomes. Risks cannot be directly observed or measured because they are potential outcomes that may or may not occur. Uncertain occurrence is a necessary, but not sufficient, condition for risk; an undesirable outcome is the other necessary condition. Probability is the most common language of uncertainty. Thus, qualitatively or quantitatively assessing the probability/likelihood of the various adverse and beneficial consequences associated with the identified risks is necessary for risk assessment. This step is most analogous to the exposure assessment task of the NRC "Red Book" or *Codex* models.

Assessing the likelihoods of the consequences associated with identified risks can often be aided by developing a risk hypothesis. A risk hypothesis is a model or scenario that credibly explains how the source of the risk can lead to the consequences of concern by identifying the appropriate sequence of uncertain events that must occur for this to happen. The likelihood assessment characterizes the chance of that sequence of events occurring. Think of this step as estimating the probability that a risk target (person or thing) will be exposed to the hazard that can cause harm. Alternatively, it is estimating the probability that an opportunity does (or does not) yield a favorable outcome.

In the relatively loose, that is, nontechnical, language of risk, probability and likelihood are used as synonyms. Some draw a nontechnical distinction that uses probability for quantitative estimates and likelihood for qualitative estimates. More rigorously, likelihood is not a probability but we yield to the use of these words as synonyms in this text.

Three simple risk hypotheses are illustrated in Figures 4.4 through 4.6. The first example in Figure 4.4 is a risk model for estimating expected annual flood damages. For the upper right quadrant it is assumed that property damage (consequence), measured in dollars, increases with water depth. The upper left quadrant shows the volume of water flow (hazard) required to reach the corresponding depths of water. On the lower left, the likelihoods of the various flows being equaled or exceeded in a year are shown. These three relationships* together yield the fourth relationship (damage-frequency) in the lower right quadrant, which when integrated provides a measure of property damages called expected annual damages. The likelihood characterization is derived from the middle two quadrants.

A second risk hypothesis is seen in Figure 4.5. This shows the presumed relationship between a human activity (logging), the stressors it creates, and the adverse effects that can result in a forest environment (EPA 1998). A likelihood assessment would require estimating the likelihood of each of these model elements.

The risk hypothesis embodied in the FDA risk assessment on *Vibrio parahaemolyticus* in raw oysters (FDA 2005) is shown in Figure 4.6. The likelihood characterization is more complexly woven through elements of this hypothesis.

It is essential to identify the significant uncertainties and to analyze their potential impact on the likelihoods of the risks. This may be done qualitatively or quantitatively, in concert with the level of detail in the overall risk assessment.

4.4.4.1 Exposure Assessment

The likelihood characterization includes the special subset of "exposure assessments" that virtually all health-related risk assessments require. An exposure assessment estimates the intensity, frequency, and duration of exposure to a risk agent. Exposure assessments identify the relevant pathways by which a human or other population is exposed to a hazard. The exposure assessment is often the most difficult part of a risk assessment, because the pathways can be both numerous and complex. They are also plagued by knowledge uncertainty and natural variability.

Exposures can be monitored directly, when direct measurement of the individual's exposure by instruments is possible. Otherwise we are restricted to measuring factors that affect exposure rather than the exposure itself. These are indirect methods of monitoring. Spatial and temporal variations are often important considerations in exposure assessments. Models used to capture the relevant aspects of an exposure pathway can be quite complex.

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* Adapting the terminology of the NRC definition of risk assessment, the depth-damage curve is a dose-response relationship. The depth-flow and flow-frequency curves comprise an exposure assessment. The damage-frequency curve is a risk characterization.

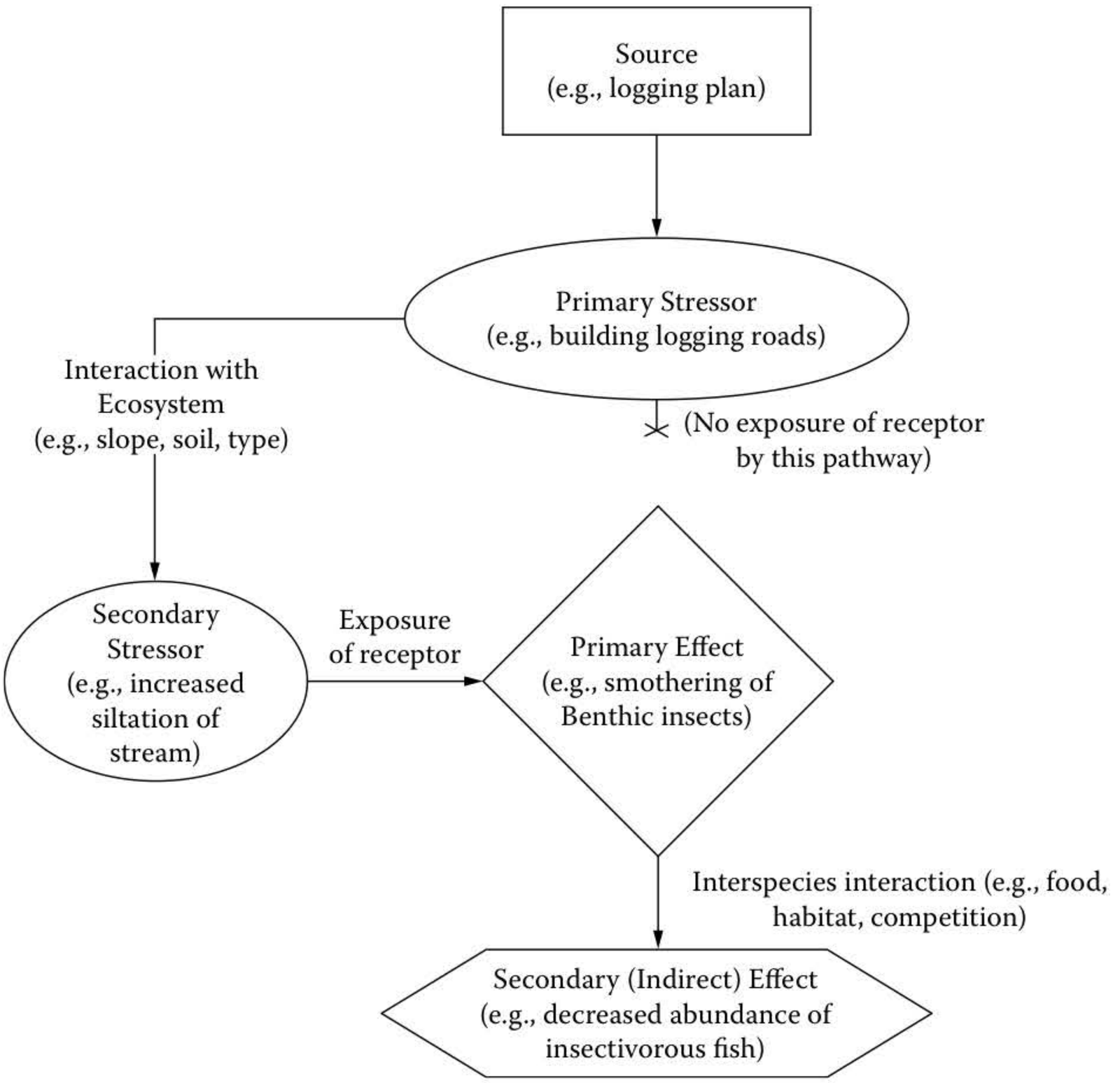

FIGURE 4.5 Conceptual model for logging forest products. (From Environmental Protection Agency. 1998. *Federal Register* 63 (93): 26846–26924.)

A general exposure equation adapted from the EPA (Covello and Mumpower, 1985) is:

$$\text{Intake} = \frac{\text{Concentration} \times \text{Contact rate} \times \text{Exposure frequency} \times \text{Exposure period}}{\text{Body weight}} \tag{4.1}$$

Here, intake is defined as mg/kg of body weight per some duration of exposure. The concentration of the risk agent (e.g., a chemical) in a medium during the exposure period is multiplied by the amount of contaminated medium contacted per unit of time or per event to get the amount of risk agent per exposure. The exposure frequency (days per year, for example) is multiplied by the exposure period (number of years) to get the duration of the exposure. The product of these two values (amount of risk agent and duration of exposure) is divided by body weight to get a dose to which one is exposed. This dose may then feed into a dose-response relationship, as discussed previously.

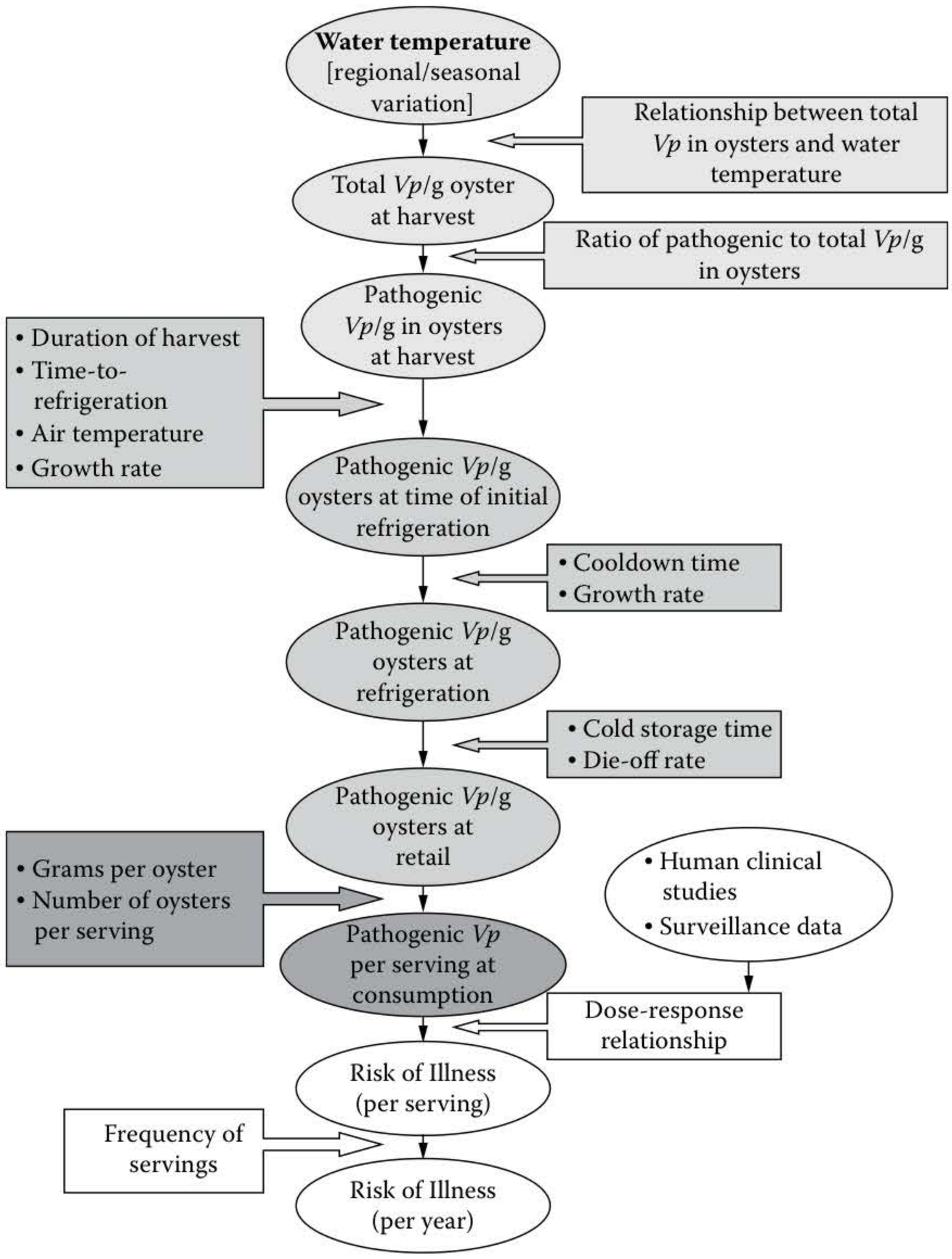

FIGURE 4.6 Schematic representation of the *Vibrio parahaemolyticus* risk assessment model. (From Food and Drug Administration. 2005. *Quantitative Risk Assessment on the Public Health Impact of Pathogenic Vibrio Parahaemolyticus in Raw Oysters*. College Park, MD: Center for Food Safety and Applied Nutrition. http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm050421.htm.)

In the event of a microbial exposure, a general exposure equation might be:

$$\begin{aligned}\text{Intake} = {} & \text{Concentration of pathogen per medium weight} \\ & \times \text{Total weight of medium}\end{aligned} \tag{4.2}$$

The resulting number of cells or colony-forming units provides an estimate of the dose, which might have an associated probability of an adverse health effect if a dose-response relationship is available.

4.4.5 Risk Characterization

Risk characterization is where many of the risk manager's questions usually get answered. Risk characterization typically includes descriptions of the probability of occurrence and the severity of adverse consequences associated with hazards, as well as the magnitude of potential gains from opportunities identified based on the evidence and analysis in all the preceding steps. Risks can be characterized qualitatively or quantitatively.

Characterizations include one or more estimates of risk and their accompanying risk descriptions. A risk estimate is an estimate of the likelihood and severity of the adverse effects or opportunities, which addresses key attending uncertainties. Quantitative estimates are numerical in nature and are usually preferred over narrative qualitative estimates. Risk estimates should include all the relevant aspects of the risk, which may encompass existing, future, historical, reduced, residual, new, transformed, and transferred risks. A risk description is a narrative explanation and depiction of a risk that bounds and defines a risk for decision-making purposes. The story that accompanies the risk estimate is what places it in a proper context for risk managers and others to understand.

There are different approaches to risk characterization. The choice of an approach depends on the needs, objectives, and questions of the risk managers. Any good risk characterization will convert the scientific evidence base into a statement of risk that answers the manager's questions. It is convenient to think of the different risk characterization approaches as running along a continuum from qualitative to quantitative. Between the two lie semi-quantitative risk characterizations, which are sometimes useful.

It is during the risk characterization that the overall importance of the various uncertainties encountered throughout the risk assessment begins to come into focus. Risk characterization should include sensitivity analysis or formal uncertainty analysis commensurate with the nature of the risk assessment.

4.4.6 Assess Effectiveness of Risk Management Options

In most cases, risk assessors will be asked to estimate risk reductions attributable to the risk mitigation options (RMOs) under consideration. In some situations, assessors or others may be asked for additional evaluations of the RMOs along with the evaluation of RMO efficacy. These evaluations might include economic costs and benefits, environmental impacts, social impacts, legal ramifications, and the like.

EXAMPLE: RISK DESCRIPTION AND RISK ESTIMATE

The 'risk per annum' is the predicted number of illnesses (gastroenteritis alone or gastroenteritis followed by septicemia) in the United States each year. As shown in the Summary Table, for each region, the highest number of predicted cases of illnesses is associated with oysters harvested in the summer and spring and the lowest in the winter and fall. Of the total annual predicted *Vibrio parahaemolyticus* illnesses, approximately 92% are attributed to oysters harvested from the Gulf Coast (Louisiana and non-Louisiana states) region in the spring, summer, and fall and from the Pacific Northwest (intertidal) region

in the summer. The lower numbers of illnesses predicted for the Northeast Atlantic and Mid-Atlantic oyster harvests are attributable both to the colder water temperatures and the smaller harvest from these regions. The harvesting practice also has an impact on the illness rate. Intertidal harvesting in the Pacific Northwest poses a much greater risk than dredging in this region (192 vs. 4 illnesses per year). This is likely attributable to elevation of oyster temperatures during intertidal exposure leading to *Vibrio parahaemolyticus* growth."

SUMMARY TABLE

Predicted Mean Annual Number of Illnesses Associated with the Consumption of *Vibrio Parahaemolyticus* in Raw Oysters

Region	Mean Annual Illnesses[a]				
	Summer	Fall	Winter	Spring	Total
Gulf Coast (Louisiana)	1,406	132	7	505	2,050
Gulf Coast (Non-Louisiana)[b]	299	51	3	193	546
Mid-Atlantic	7	4	<1	4	15
Northeast Atlantic	14	2	<1	3	19
Pacific Northwest (Dredged)	4	<1	<1	<1	4
Pacific Northwest (Intertidal)[c]	173	1	<1	18	192
TOTAL	1,903	190	10	723	2,826

Source: Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters (FDA, 2005).

[a] Mean annual illnesses refers to the predicted number of illnesses (gastroenteritis alone or gastroenteritis followed by septicemia) in the United States each year.

[b] Includes oysters harvested from Florida, Mississippi, Texas, and Alabama. The time from harvest to refrigeration in these states is typically shorter than for Louisiana.

[c] Oysters harvested using intertidal methods are typically exposed to higher temperature for longer times before refrigeration compared with dredged methods.

EXAMPLE: EFFECTIVENESS OF RMOs

SUMMARY TABLE

Predicted Mean Number of Illnesses per Annum from Reduction of Levels of Pathogenic *Vibrio Parahaemolyticus* in Oysters

Region	Predicted Mean Number of Illnesses per Annum			
	Baseline	Immediate Refrigeration[a]	2-log Reduction[b]	4.5-log Reduction[c]
Gulf Coast (Louisiana)	2,050	202	22	<1
Gulf Coast (Non-Louisiana)	546	80	6	<1

Mid-Atlantic	15	2	<1	<1
Northeast Atlantic	19	3	<1	<1
Pacific Northwest (Dredged)	4	<1	<1	<1
Pacific Northwest (Intertidal)	192	106	2	<1
TOTAL	2,826	391	30	<1

Source: Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters (FDA, 2005).

[a] Represents refrigeration immediately after harvest; the effectiveness of which varies both regionally and seasonally and is typically approximately 1-log reduction.

[b] Represents any process which reduces levels of *Vibrio parahaemolyticus* in oysters 2-log, for example, freezing.

[c] Represents any process which reduces levels of *Vibrio parahaemolyticus* in oysters 4.5-log, for example, mild heat treatment, irradiation, or ultra-high hydrostatic pressure.

Typically, the existing level of risk is assessed, and if it is judged to be unacceptable, it will be reduced to a tolerable level if it cannot be eliminated. Often the unspoken "default" level of tolerable risk is as low as reasonably achievable. In other instances, risks are reduced to the point where the costs of further reductions clearly outweigh the benefits of additional risk reductions.

In some decision settings the trade-offs among risk reduction, cost, and other criteria are more complex, and an array of RMOs may be under consideration. In these situations it is usually desirable to use a "with" and "without" risk management option comparison, as described in the previous chapter, along with a more formal trade-off analysis.

Considering residual, new, transferred, and transformed risk at the time that risk reductions are estimated is likely to be efficient. In some instances, RMOs will be reasonably well formulated at the time that the risk assessment is initiated. In other situations, due to the iterative nature of risk analysis science, RMOs may not even be identified until well after the risk assessment has begun. In other cases it may not even be appropriate to begin to formulate RMOs until after the risk has been initially assessed and judged to be unacceptable. For these reasons, this RMO assessment step, often considered an integral part of risk characterization in some descriptions of risk assessment, is separated out here. Uncertainties concerning the performance or efficacy of an RMO in reducing unacceptable risks to acceptable or tolerable levels should be investigated and documented so that risk managers and other interested parties may be made aware of them.

4.4.7 Communicate Uncertainty

It is not enough for risk assessors to identify and investigate the significance of the instrumental uncertainties identified throughout the risk assessment. They must communicate its significance for decision making to risk managers. Methodologies for effectively conveying information about what is known with certainty and

which remaining uncertainties could affect the risk characterization or the answers to the risk manager's questions need to be developed and carried out. When it comes to decision making, it is better to have a general and incomplete map, subject to revision and correction, than to have no map at all (Toffler 1990). But those using the risk assessment map to make decisions must know its limitations.

Characterizing the significance of the instrumental uncertainties in a risk assessment is critical to informed decision making. The NRC (1994) said, "Uncertainty forces decision makers to judge how probable it is that risks will be overestimated or underestimated." This is important for risk managers to understand, as they determine the need for and appropriate choice of an RMO.

Characterizing uncertainty can also support the informed consent of those affected by risk management decisions. When people are asked to live behind a levee or near a nuclear power plant, to get a vaccination for a seasonal flu, or to board an airplane, they have a right to know the limitations of the risk management measures taken on their behalf as well as the limitations of the information on which those measures were based. Characterizing uncertainty is essential to the transparency of a risk assessment. Transparency enhances the credibility of the process, improves the defensibility of actions taken or not taken, and empowers affected individuals to make better choices for themselves in response to the risks that remain.

Uncertainty analysis also identifies important data gaps, which can be filled to improve the accuracy of the risk assessment and, hence, support improved decision making. Risk assessors should communicate their degree of confidence in the risk assessment they have done so that risk managers can take this into consideration for decision making. To do this, risk assessors should explicitly address natural variability and knowledge uncertainty and their potential impacts on the risk estimate in every risk characterization, qualitative or quantitative. All assumptions should be acknowledged and made explicit. The impacts of these assumptions on the risk characterization and subsequently the manager's use of the risk assessment in decision making are to be thoroughly discussed. Assessors should describe the strengths and limitations of the assessment along with their impacts on the overall assessment findings. Assessors should also say whether they believe the risk assessment adequately addresses the risk manager's questions.

The International Programme on Chemical Safety (IPCS, 2008) has proposed four tiers or levels of uncertainty analysis, which provide a useful way to think about this activity. These are:

- Tier 0: Default assumptions
- Tier 1: Qualitative but systematic identification and characterization of uncertainty
- Tier 2: Quantitative evaluation of uncertainty making use of bounding values, interval analysis, and sensitivity analysis
- Tier 3: Probabilistic assessment with single or multiple outcome distributions reflecting uncertainty and variability

Each of these tiers entails different responsibilities for the risk assessors. In best practice, default assumptions will rarely be used. Uncertainty can be discussed in

the absence of quantitative data. It is always possible to tell decision makers what is known with certainty, what we suspect based on incomplete data, and what we assume based on inadequate or missing data. The key is to adopt a systematic approach to communicate the uncertainty qualitatively. This will help to ensure that the job is done adequately.

Quantitative risk assessments lend themselves to numerical characterizations of the uncertainty attending risks. Deterministic risk characterizations can be supplemented by offering high/low, optimistic/pessimistic, or more formal statistical confidence interval estimates of decision criteria and risks estimated in the assessment. Using interval estimates for uncertain inputs and tracking their impact on critical outputs is a feasible way to identify and communicate what is most important. In probabilistic risk assessment, the challenges of communication are greater, because although there is usually more useful information, it is quantitatively complex and problematic for many risk managers and stakeholders who lack training in interpreting and understanding probabilistic data. Examples of both qualitative and quantitative risk assessment techniques are found in later chapters.

The basic problem in risk assessment is that our data are incomplete and we are uncertain about many things. None of this absolves us of the need to make decisions, however. Risk assessment is a process through which complex, incomplete, uncertain, and often contradictory evidence and scientific information are made useful for decision making (NRC, 1983). As a decision-support framework, risk assessment fills the gap between the available evidence and the RMOs being considered to respond to the risks identified. Risk managers must understand those gaps, how they were bridged, and their significance for decision making. It is the assessor's job to explain all of this to them.

4.4.8 Document the Process

Risk assessment is initiated to support decision making that solves problems and realizes opportunities. Substantial resources are dedicated to risk assessment, and it is essential that we carefully and effectively document its findings. It is equally important to document the basis for the risk management actions taken or not taken. Think of documentation as a set of different communications that authenticate and support the results of the risk management activity. The hope is that risk management decisions will be directly linked to the evidence found in the risk assessment documentation.

Assessors are well advised to document the assessment process as it progresses rather than to wait until it has been finished to write up a report. Risk assessment generally progresses in an iterative fashion. Our understanding of problems evolves as the assessment progresses. Analysis is refined as data gaps are filled and models are built. Numerous people will be involved at many points along the way. It is often easier to have assessors document their findings as they go, revising them as new data and analysis warrant. Chapter 21 discusses strategies for how to tell the story of a risk assessment or other risk management activity.

TELLING YOUR STORY

Story telling is underestimated as an effective communication skill. Stop listing facts and dumping data into reports and tell a simple story well. We all remember engaging stories from our childhood and they had three key elements in common:

An engaging beginning…once upon a time
An interesting middle…consider a talking mirror
A satisfying ending…they all lived happily ever after

Tell the story by structuring the facts so they have a narrative quality. Let your documentation be a journey with a narrative theme. Good stories are simple and let the facts speak for themselves.

Documentation need not be restricted to a written report. Nontraditional risk assessment documentation methods might include:

- Interactive web sites
- Interactive digital media
- Video reports
- Workshops
- Chat rooms
- Wikis
- Discussion groups
- Electronic files
- Training in the use of the risk assessment model
- Live online briefings
- Page limits on written documents

Identify your audience and choose a suitable documentation format.

4.5 RISK ASSESSMENT MODELS

The generic risk assessment tasks you've been reading about have been standardized for a variety of applications and communities of practice (CoP). The food-safety community, for example, has been aggressive in trying to harmonize risk assessment methods in part to facilitate international trade. They, like other CoPs, have promulgated models for use by their constituents. A few of these models are presented in this section to illustrate the diverse range of ways in which these rather generic risk assessment activities are being formalized for specific applications. The details of the model are less important than the overarching point that risk assessors exercise a great deal of latitude in the specific ways they do risk assessments.

The *Codex Alimentarius* represents the international food-safety community. They employ a familiar risk assessment model, shown in Figure 4.7. Within or alongside

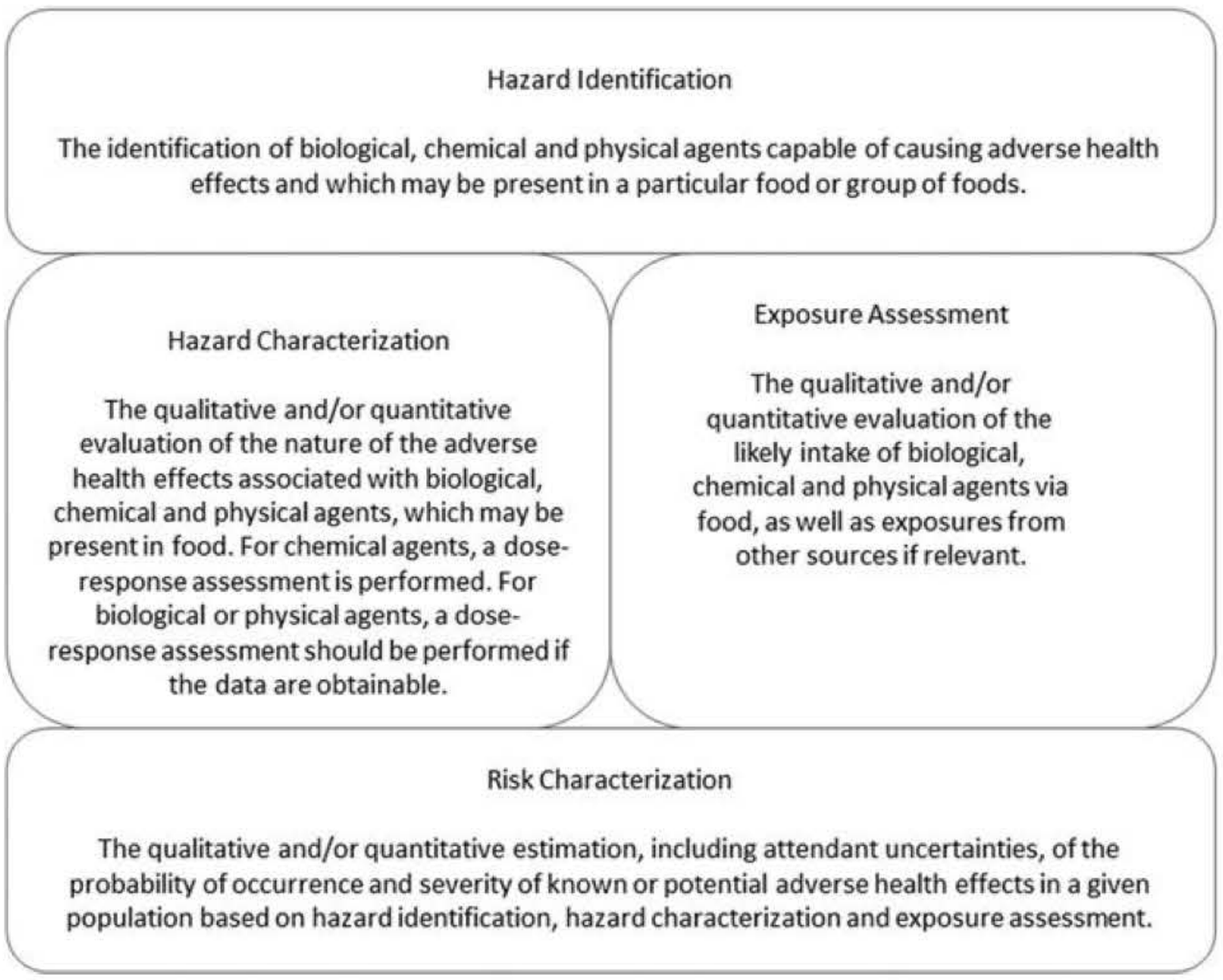

FIGURE 4.7 Generic Codex description of the risk assessment components. (Food and Agricultural Organization. 2006. *United Nations. FAO Food and Nutrition Paper 87. Food safety risk analysis: A guide for national food safety authorities*. Rome, Italy: FAO.)

of this framework, CoPs have developed distinctive models and methodologies for different hazards like food-additive chemicals, pesticides, microbiological hazards, food nutrients, antimicrobial resistance, and genetically modified organisms.

Chemical food additives are evaluated using a safety assessment, which on the surface looks quite different from the generic model of this chapter. Its six steps comprise the following: test toxicity, identify NOAEL, choose a safety factor, calculate the ADI, calculate the EDI, and characterize the risk with the ratio EDI/ADI.

A conceptual application of the model is presented in Figure 4.8. Toxicity studies, most often based on animal data, are used to identify a level of exposure to a chemical, usually measured in a lifetime dose that causes no adverse effects. This is equivalent to a hazard characterization. In the example in Figure 4.8, this level is 5 mg per kg of body weight daily for a lifetime.

To extrapolate from animal studies and their typically high doses to humans and their typically low doses, an uncertainty factor (in the example, 100) is used to identify an ADI. Thus, a NOAEL of 5 mg/kg/day/lifetime divided by 100 yields an ADI of 0.05 mg/kg/day/lifetime.

A survey of consumption behavior yields the daily consumption of the additive for a high-end consumer, say the 90th percentile consumer of this additive, and this is used as the EDI. This constitutes the exposure assessment. The risk characterization

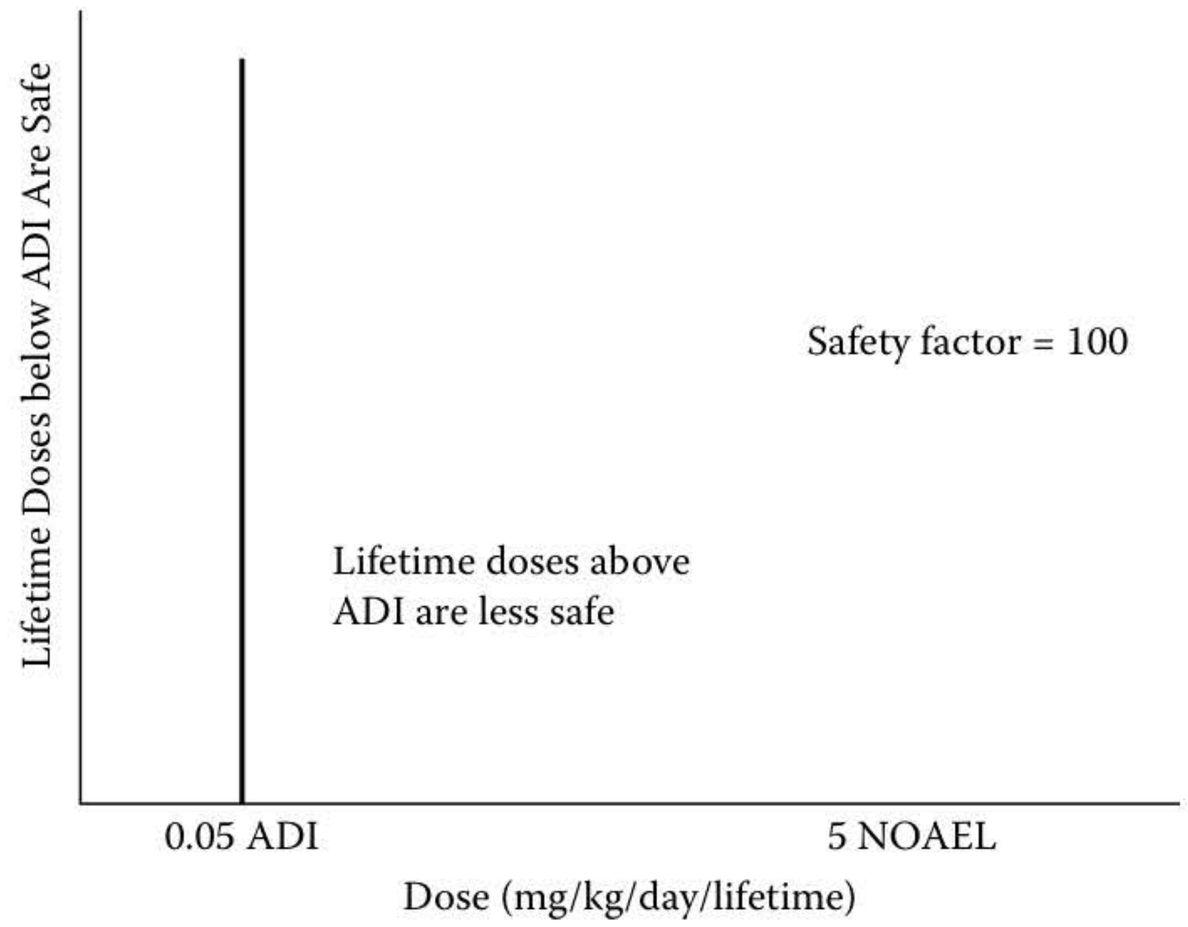

FIGURE 4.8 Representation of the food-additive safety assessment model.

is completed by simply comparing the EDI to the ADI. There is no effort to explicitly identify the likelihood of an adverse outcome in this assessment model.

Pesticide chemical risks are somewhat similar, although the language changes a little:

- Identify pesticide residue of interest
- Undertake toxicity studies of substance if needed
- Determine the NOAEL
- Select a safety factor or uncertainty factor to extrapolate results from animals to humans
- Calculate the ADI
- Identify a suitable index of residue levels to predict residue intake—usually the maximum residue limit (MRL)
- Estimate the dietary intake of the residue (exposure assessment)
- Compare exposure to ADI (when exposure exceeds ADI, some sort of risk mitigation is required)

Note that although the language differs in each, they all exhibit elements of the previously described generic process. The hazard is identified; the consequences and likelihoods (or exposures) are assessed; and it is all pulled together in some sort of characterization of the risk.

Antimicrobial-resistant risk assessment is used to evaluate the safety of new animal drugs with respect to concerns for human health. Exposing bacteria in animals to antimicrobial drugs could increase the number of resistant bacteria to the point where it reduces the efficacy of antimicrobial drugs prescribed for human health. This model, shown in Figure 4.9 and taken from FDA Guidance Document 152 (FDA, 2003), suggests a qualitative approach for identifying new drugs as potentially high, medium, or low risks for human health.

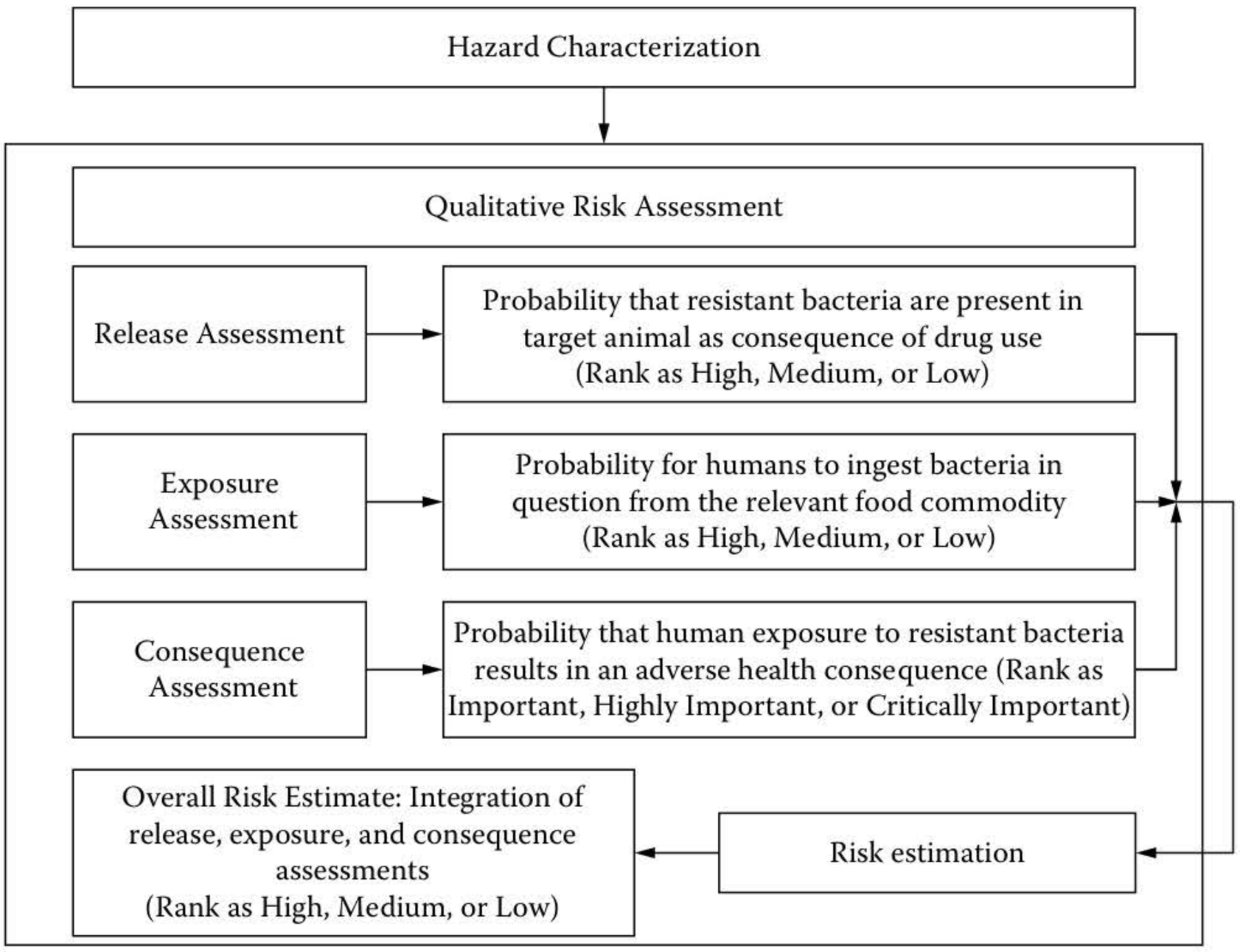

FIGURE 4.9 Components of a qualitative antimicrobial-resistance risk assessment. (Food and Drug Administration. 2003. *Guidance for Industry Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern. No. 152*. Rockville, MD: Center for Veterinary Medicine. http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf.)

Food safety is not the only COP to have developed standardized mental models to guide thinking about risk assessment. The U.S. EPA (1998) developed the model shown in Figure 4.10 for ecological risk assessment. Note that it differs from the four-step definition of the "Red Book" but has clear roots in that model as well. The "Red Book" model was developed principally for assessing human health risks due to chemicals in the environment. The ecological model expands the notion of hazards to include a broad class of stressors and it includes adverse effects on ecosystems. It has three main steps: problem formulation, analysis, and risk characterization.

Hazards are identified as stressors in problem formulation. The analysis step is divided into characterizations of exposure and ecological effects, the latter of which is evocative of the hazard characterization step. The risk characterization step serves the familiar purpose. The point here is that although the models vary in their language and details, they remain firmly committed to the principles articulated in the tasks identified earlier in this chapter.

If you search Internet images using the phrase "risk assessment model," you'll see thousands of different models in millions of hits. Many risk assessment problems are so unique that they cannot be usefully fit to any of the existing mental models for risk assessment. It is always wise to familiarize yourself with any standardized

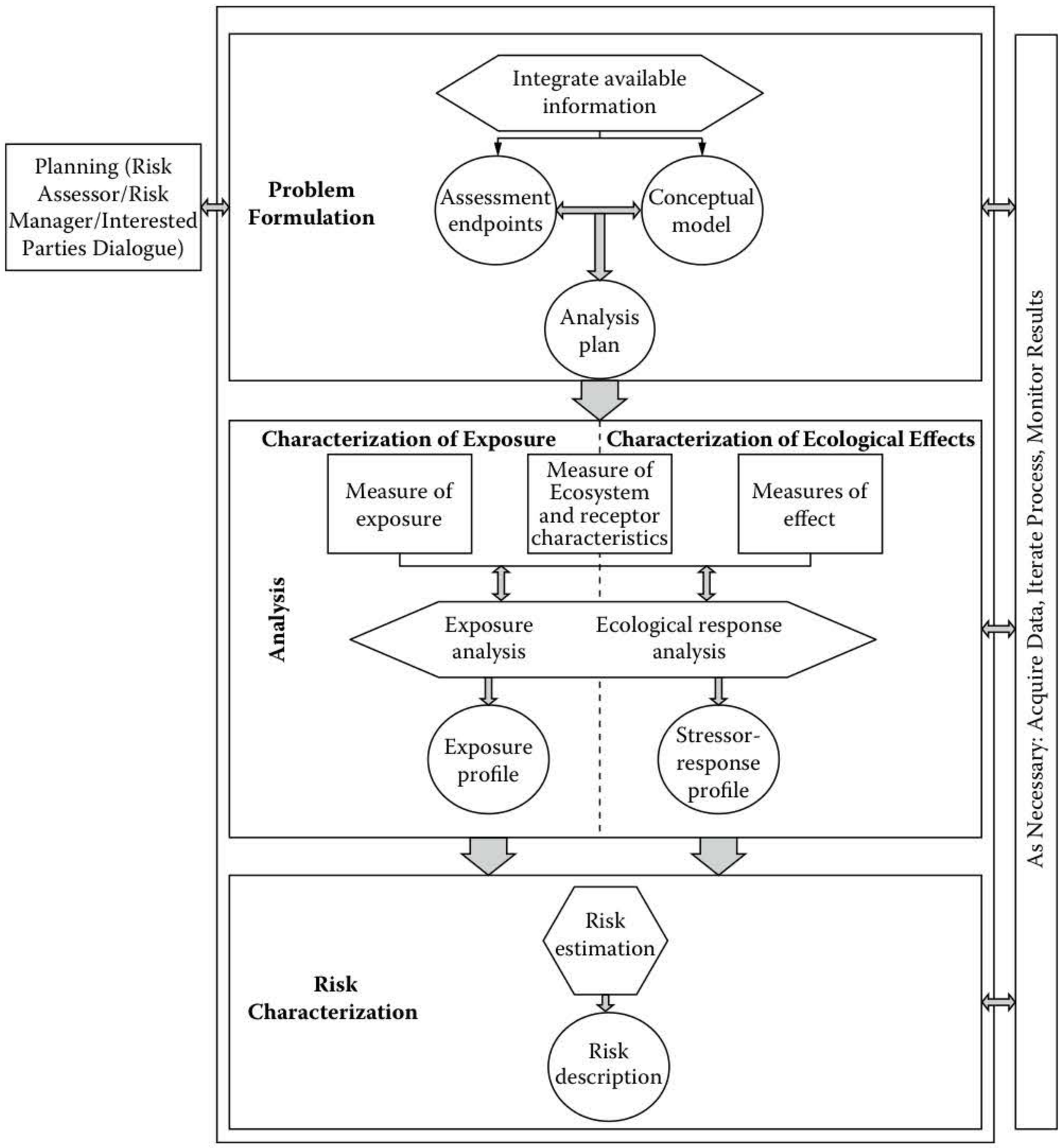

FIGURE 4.10 Ecological risk assessment framework, with an expanded view of each phase. (From Environmental Protection Agency. 1998. *Federal Register* 63 (93): 26846–26924.)

assessment models used by your CoP. More importantly, you should always feel free to adapt these models or to develop your own mental model when it suits your decision-making needs to do so. If you flounder at times, keep coming back to the four informal questions: What can go wrong? How can it happen? What are the consequences? How likely is it? Find a way to ask and answer these questions and you will be doing risk assessment, formal model or not.

Very often an organization has a model with a well-established structure. Consider the model in Table 4.1, which is used to estimate the costs of a dredging project that includes marsh creation for disposal of the dredged material. It is not difficult to imagine that risk managers may be concerned with the risk of a cost overrun. There is no need here to develop a conceptual model. In this instance, the structure of the model is well established and we need only reach into the risk assessor's toolbox for the appropriate techniques for assessing this risk using our four informal questions.

TABLE 4.1
Channel Modification Dredging Cost Estimate

Account Code	Description	Quantity	Unit	Unit Price	Amount
01	Lands and damages	0	LS	—	—
02	Relocations				
	Lower 20 pipeline, 653 + 00	427	LF	$843.66	$359,979
	Remove 8″ pipeline, 678 + 00	986	LF	$47.85	$47,197
02	*Total—relocations*				*$407,176*
06	Fish and wildlife facilities (mitigation)				
	Oyster reef creation	0	ACR	—	—
06	*Total—fish and wildlife facilities (mitigation)*				—
12	Navigation, ports, and harbors				
	Mobe and demobe	1	LS	$500,000	$500,000
	Pipeline dredging, Reach 1	576,107.00	CY	$2.43	$1,398,788
	Pipeline dredging, Reach 2	1,161,626.68	CY	$2.76	$3,209,691
	Pipeline dredging, Reach 3A	1,532,227.12	CY	$3.72	$5,693,450
	Pipeline dredging, Reach 3B	708,252.02	CY	$2.89	$2,049,398
	Scour pad, Reach 1	16,484	SY	$16.62	$273,906
	Geotubes, 30′, Reach 1	1,345	LF	$221.03	$297,192
	Geotubes, 45′, Reach 1	4,601	LF	$291.00	$1,338,995
	Scour pad, Reach 3	39,059	SY	$16.62	$649,029
	Geotubes, 45′, Reach 3	13,848	LF	$291.00	$4,029,879
12	*Total—navigation, ports, and harbors Subtotal*				*$19,440,328*
30	Engineering and design	8%			$1,587,800
31	Construction management	6%			$1,190,850
	Total project cost				*$22,626,154*

Abbreviations: LF = linear feet; LS = lump sum; CY = cubic yards; SY = square yards, ACR = acres.

For now it is sufficient to understand that there is a large class of problems that require no specific risk assessment model. Often it is sufficient to pay appropriate attention to the uncertainty that has always been present in our work. In many instances, risk assessment can mean doing what you have always done, with the exception of paying close attention to the things you do not know. Using the generic risk assessment activities described here should provide you with a serviceable model when a formal one is not available.

4.6 RISK ASSESSMENT METHODS

Any self-contained systematic procedure conducted as part of a risk assessment is a risk assessment method (Covello and Merkhofer, 1993). These methods are conveniently divided into qualitative and quantitative methods. There has been

a misperception on the parts of some and a bias on the parts of others who have suggested that qualitative risk assessment is not a valid form of risk assessment. I think it fair to say that quantitative risk assessment is preferred whenever there are data adequate to support it. It is equally fair to say that qualitative risk assessment is a valid and valuable form of risk assessment. Quantitative assessments use numerical expressions to characterize the risks, qualitative assessments do not. Examples of each are provided in later chapters.

4.6.1 Qualitative Risk Assessment

The fundamental need is to manage risk intentionally and to do that better than has been done in the past. Quantitative risk assessment is not always possible or necessary, so qualitative risk assessment is often a viable and valuable option. It is especially useful:

- For routine noncontroversial tasks
- When consistency and transparency in handling risk are desired
- When theory, data, time, or expertise are limited
- When dealing with broadly defined problems where quantitative risk assessment is impractical

A qualitative risk assessment process compiles, combines, and presents evidence to support a nonnumerical estimate and description of a risk. Numerical data and analysis may be part of the input to a qualitative risk assessment, but they are not part of the risk characterization output. Qualitative assessment produces a descriptive or categorical treatment of risk information. It is a formal, organized, reproducible, and flexible method based on science and sound evidence that produces consistent descriptions of risk that are easy to explain to others. Its value stems from its ability to support risk management decision making. If you can answer the risk manager's questions adequately and describe the risk in a narrative or categorically, then a qualitative assessment is sufficient. Uncertainty in qualitative assessments is generally addressed through descriptive narratives. Several specific qualitative risk assessment methodologies can be found in Chapter 10.

4.6.2 Quantitative Risk Assessment

Quantitative risk assessment relies on numerical expressions of risk in the risk characterization. Numerical measures of risk are generally more informative than qualitative estimates. When the data and resources are sufficient, a quantitative assessment is preferred, except where the risk manager's questions can be adequately answered in a narrative or categorical fashion.

Quantitative assessments can be deterministic or probabilistic. Deterministic assessments produce point estimates of risks. Probabilistic assessments rely on probability distributions and probability statements to estimate risks. The choice depends on the risk manager's questions, available data, the nature of the uncertainties, the skills of the

assessors, the effectiveness of outputs in informing and supporting decision makers, and the number and robustness of the assumptions made in the assessment.

Generally, quantitative risk characterizations address risk management questions at a finer level of detail and resolution than a qualitative risk assessment. This greater detail usually introduces a more sophisticated treatment of the uncertainty in the risk characterization than is found with qualitative assessment.

4.7 SUMMARY AND LOOK FORWARD

Risk assessment is where the evidence is gathered. It is the primary place where we separate what we know from what we do not know and then deal intentionally with those things we do not know. It is where we get the right science focused into the analysis and take pains to get that science right.

In general terms, risk assessment is the work you must do to answer four informal questions. What can go wrong? How can it happen? What are the consequences? How likely is it? The four primary steps that comprise a risk assessment and answer these questions are: identify the hazards and opportunities, assess the consequences, assess the likelihood, and characterize the risk. There are any number of application-specific refinements of these notions in widespread use. Recurring kinds of problems lend themselves well to the development of standardized approaches to assessing these risks.

In the best practice of risk assessment, risk managers will identify specific questions they want the risk assessment to answer. Risk assessors answer these questions and characterize the uncertainty in their assessment in ways that support risk-informed decision making. The answers to these questions can be provided in a qualitative or a quantitative manner, depending on the needs of the risk management activity.

Estimating and describing risks in the risk assessment is the critical analytical step in risk analysis. But if we are not able to communicate this often complex information to risk managers, stakeholders, and the public, all will have been for naught. The next chapter addresses the risk communication component of risk analysis. Until relatively recently, risk communication has been treated like the stepchild of risk analysis, too often an afterthought or an add-on. More recently it has begun to receive more of the attention it rightfully deserves.

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